UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE GENZYME CORP. SECURITIES LITIGATION	Consolidated Case No. 09-cv-11267 (GAO)
	JURY TRIAL DEMANDED

CONSOLIDATED CLASS ACTION COMPLAINT

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TABLE OF CONTENTS

1. This is a federal securities fraud action brought by Lead Plaintiffs Deka International S.A. Luxembourg, the City of Edinburgh Council as Administering Authority of the Lothian Pension Fund, and the Government of Guam Retirement Fund ("Plaintiffs") on behalf of themselves and a class (the "Class") consisting of all purchasers of the common stock of Genzyme Corporation ("Genzyme" or the "Company") between and including October 24, 2007 and November 13, 2009 (the "Class Period"). This action is brought against Genzyme, Henri A. Termeer, David Meeker, Alison Lawton, Mark R. Bamforth, Geoffrey McDonough, and Michael Wyzga (collectively, the "Defendants") for violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder.

2. The allegations in this Complaint are based upon information and belief, except as to allegations specifically pertaining to Plaintiffs, which are based on personal knowledge. Plaintiffs base their belief upon information uncovered through an investigation conducted by and under the supervision of Plaintiffs' attorneys into the facts and circumstances alleged herein, including, without limitation, consultation with experts on compliance with Food and Drug Administration ("FDA") regulations relating to the manufacturing of biologic drug products, as well as review and analysis of: (a) FDA correspondence and inspection reports, including materials that have only recently been disclosed publicly or were obtained by Plaintiffs through the Freedom of Information Act; (b) Genzyme's filings with the U.S. Securities and Exchange Commission ("SEC"); (c) transcripts of Genzyme's analyst and investor conference calls; (d) publicly available press releases, news articles, and other media reports disseminated by or concerning the Defendants; and (e) interviews with confidential witnesses. Except as alleged herein, the underlying information relating to Defendants' misconduct and the particulars thereof

are not available to Plaintiffs and the public and lie exclusively within the possession and control of Defendants and other Company insiders. Plaintiffs believe that further substantial evidentiary support exists for the allegations set forth below and that such support will become available after a reasonable opportunity for discovery.

SUMMARY OF ALLEGATIONS

3. This action arises from Defendants' misrepresentations and concealment concerning pervasive, systemic, and serious deficiencies in Genzyme's flagship Allston plant, which produced the drugs responsible for nearly half of its annual revenues As detailed herein, these manufacturing issues resulted in multiple notices from the FDA, an unprecedented two viral contamination outbreaks in less than a year, a lengthy shutdown of the plant, and, ultimately, yet another contamination at Allston involving the adulteration of Genzyme's most important medicines with at least three different types of foreign substances, including dangerous metal shards.

4. Throughout the Class Period, Defendants portrayed Genzyme as a responsible pharmaceuticals company that produced medicines in a safe and effective manner in compliance with the FDA's Current Good Manufacturing Practices ("CGMP"), and thus capable of generating reliable revenues through the manufacture and sale of its core products, and of obtaining FDA approval for "Lumizyme," a highly-touted variant of one of Genzyme's core products. Unbeknownst to investors, however, Defendants consistently concealed the severity and pervasiveness of Genzyme's compliance problems (especially at Allston), the near-total failure of their "efforts" to adequately address known compliance deficiencies, and their inability to satisfy FDA conditions for approval of Lumizyme. Genzyme's rampant compliance deficiencies not only led to an extraordinary series of viral outbreaks and other serious contamination events at Genzyme, but also caused the Company's investors to suffer significant

losses as the truth concerning the nature and extent of Genzyme's compliance issues was gradually disclosed.

5. The safety and efficacy of Genzyme's manufacturing operations was highly material to investors, who regarded information about drug contamination and manufacturing problems as critical to the Company's business. Further, because Genzyme's drug products were not chemical compounds, but were instead composed of living biological organisms (which are classified as "biologics"), Genzyme's drug products were particularly susceptible to contamination. Accordingly, the effectiveness of Genzyme's anti-contamination practices and procedures were especially material to investors.

6. During the Class Period, however – and as subsequently confirmed by the Defendants' own admissions and FDA documents – Defendants consistently concealed from investors the severity of the Company's manufacturing problems at the Allston plant and other compliance-related deficiencies. Indeed, Defendants' own statements effectively concede that (a) they knew about the extent and severity of these problems at all material times, and (b) that they nonetheless refused to disclose any information about these problems until well into the Class Period – and that even then they continued to repeatedly mislead investors as to full nature, extent, and gravity of the Company's compliance problems. These serious deficiencies included, *inter alia*, the following:

- Overloaded Facility: Defendants placed excessive production demands on the Allston plant, imposing production levels well beyond the capacity of the plant and in violation of FDA regulations;

- Obsolete Equipment: The equipment that Genzyme used to manufacture medicines at Allston was outdated, deteriorated and inadequate to ensure compliance with FDA regulations;

- Failure to Properly Maintain Equipment: Genzyme failed to follow required procedures to maintain and clean the Allston facility's drug manufacturing equipment;

- Failure to Adequately Monitor Product for Contamination: Genzyme failed to adequately screen its products during the manufacturing process, as required to ensure the absence of microbiological contamination;

- Mishandling of Raw Materials: Genzyme failed to adequately maintain and inspect the raw materials that it used to manufacture medicine, as required to ensure that its medicines were not adulterated;

- Unsterile Airflow System: The Allston facility did not comply with FDA regulations designed to ensure that contaminated air did not flow into sterile areas used for product manufacturing;

- Inadequate and/or Manipulated Quality Control Testing: Genzyme employees manipulated internal testing for contamination to cover up flawed anti-contamination procedures; and

- Lack of Adequate Training and Record Keeping: Genzyme did not train its Allston employees in proper anti-contamination procedures and failed to keep required records.

7. The problems at Genzyme's Allston facility were particularly important to investors not only because the drugs produced at Allston accounted for most of the Company's revenue, but also because FDA approval of Lumizyme depended on the FDA concluding that the Allston facility (where this drug was to be manufactured) complied with applicable FDA regulations. But until the end of the Class Period, investors never knew that conditions at Allston made FDA denial of Genzyme's application for its highly anticipated Lumizyme product virtually inevitable.

8. Given how vital Allston's plant operations were to the Company and given the sheer breadth and severity of its problems, it is simply implausible that Defendants could not have been aware that conditions at the Allston plant fell far short of complying with CGMP – especially where FDA regulations expressly impose primary legal responsibility for monitoring and ensuring compliance with CGMP directly on senior corporate management. Nor can the Defendants plausibly deny their knowledge of undisclosed contamination outbreaks and the contents of official FDA inspection reports. As detailed herein, moreover, Defendants' own

statements also strongly confirm their *scienter*. For example, as defendant Termeer, Genzyme's President, Chairman, and Chief Executive Officer ("CEO"), belatedly admitted in late 2009, he knew that the aging Allston plant was being "overloaded" during the Class Period, and other senior executives have conceded that serious problems flagged by the FDA were "not new."

9. Even before the start of the Class Period, the FDA had notified Genzyme on multiple occasions that its lack of controls increased the risk of manufacturing problems and that it was senior management's responsibility to investigate those problems. For example, a 2001 FDA warning letter addressed to defendant Termeer stated that control defects identified therein "may be symptomatic of serious underlying problems within your establishment's quality system. You are responsible for investigating and determining the causes of the violations." In another warning letter issued in September 2007 – just before the commencement of the Class Period – the FDA warned Termeer that "based on FDA's experience, there is a high probability that the observed CGMP deviations, if not corrected, would substantially increase the risk of future product failures." Defendants were thus on notice that they needed to pay close attention to identifying and correcting deficiencies in Genzyme's manufacturing practices and procedures, and that they had direct and primary responsibility to ensure that the Company's quality control systems were operating appropriately.

10. By October 2008, Defendants had received additional explicit and detailed warnings from the FDA concerning the disastrous condition of the Allston plant in particular. On October 10, 2008, the FDA completed a month-long inspection of the Allston plant in connection with the pending Lumizyme application. At the conclusion of this inspection, the FDA issued Genzyme a Form 483 (the "October 2008 483"), which is the FDA's formal post-inspection report detailing the FDA's observations during the course of its assessment. The

October 2008 483 specifically identified numerous manufacturing deficiencies at the Allston plant, including the defective maintenance of purification and sterilization equipment; the regular use of manual intervention when aged equipment malfunctioned; non-sterile airflow into sterile areas; the absence of appropriate record-keeping and anti-contamination training procedures; and inadequate controls for the monitoring and handling of the materials used in manufacturing the biologic agents produced an the Allston facility.

11. Despite the significance of the FDA's conclusions set forth in the October 2008 483, and despite the clearly adverse implications of this information for the pending Lumizyme application, Defendants did not disclose the existence of the October 2008 483 or the substance of the FDA's concerns with the deficiencies of the Allston plant until months later. Instead, Defendants continued to conceal these problems from the investing public, and to falsely reassure investors concerning the state of the Company's discussions with the FDA about its pending application for FDA approval Lumizyme.

12. Defendants failed to reveal even the existence of the October 2008 483 until March 2009, shortly after the FDA had issued a warning letter reiterating and summarizing some of its earlier concerns about compliance issues at Allston. Following disclosure of the warning letter and the existence of the prior Form 483, however, Defendants continued to conceal the true depth and severity of its compliance problems, and falsely reassured investors that any deficiencies at Allston facility were already well on their way to being cured.

13. On June 16, 2009, Defendants were forced to disclose that the Allston plant had experienced a viral contamination outbreak that required the plant to be temporarily shut down for decontamination – and also belatedly disclosed for the first time that the Company had recently experienced two similar outbreaks. In response to these disclosures, the shares of

Genzyme stock fell sharply, from $55.62 to $52.75 per share. However, once again Defendants failed to disclose the full nature and extent of its compliance problems, and falsely reassured investors, for example, that these developments would not threaten approval of its pending Lumizyme application and would not require further FDA re-inspections of the Allston facility. Accordingly, the fraud continued.

14. On November 13, 2009 (the last day of the Class Period), the FDA and Genzyme jointly announced yet another contamination outbreak at the Allston plant and issued a warning to doctors worldwide alerting them that five medicines produced at Allston – including Genzyme's three top revenue producing drugs – had been found to contain unacceptably high levels of potentially harmful foreign substances, including stainless-steel fragments, rubber foam, and other unspecified materials. As the Associated Press reported: "federal health regulators have found tiny particles of trash in drugs made by Genzyme, the second time this year the biotechnology company has been cited for contamination issues." In response to these disclosures, investors promptly (and correctly) determined that there was no reasonable prospect that the FDA would approve the pending Lumizyme BLA anytime soon, that Defendants had utterly and completely failed to come even close to adequately addressing FDA concerns about the Allston plant, and that the depth and severity of the compliance problems at Allston were significantly greater than Defendants had ever previously disclosed. Accordingly, the shares of Genzyme fell once again, closing on November 13, 2009 at $49.28 per share – a far cry from Genzyme's Class Period high of $83.25 on August 14, 2008.

15. Later that same day, Genzyme also received yet another Form 483 (the "November 2009 483") listing an extraordinary ***49 instances of manufacturing deficiencies at***

Allston. It also received a separate letter from the FDA rejecting the pending Lumizyme application, citing the myriad serious compliance problems at Allston as the reason.

16. Defendants' false and misleading statements and false assurances concerning the true state of the Allston facility and related matters caused Genzyme's stock to trade at artificially inflated prices throughout the Class Period. By this action, Lead Plaintiffs, on behalf of themselves and the members of the Class, now seek to recover damages arising from the substantial losses suffered as a result of Defendants' misconduct.

JURISDICTION AND VENUE

17. The claims asserted in this Complaint arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act, 15 U.S.C. §§ 78j(b) and 78t(a), and Rule 10b-5 promulgated thereunder, 17 C.F.R. § 240.10b-5.

18. This Court has jurisdiction over the subject matter of this action pursuant to Section 27 of the Exchange Act, 15 U.S.C. § 78aa, and 28 U.S.C. §§ 1331 and 1337.

19. Venue is proper in this Judicial District pursuant to Section 27 of the Exchange Act, 15 U.S.C. § 78aa, and 28 U.S.C. § 1391(b). Genzyme's corporate headquarters are located in this District and many of the acts and transactions alleged herein occurred in substantial part in this District.

20. In connection with the acts, misconduct and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to the United States mails, interstate telephone communications and the facilities of a national securities exchange.

PARTIES

I. Lead Plaintiffs

21. Lead Plaintiff Deka International S.A. Luxemburg ("DIL") is an investment fund management company established under the laws of Luxembourg and is a 100%-owned subsidiary of DekaBank Deutsche Girozentrale ("DekaBank"), one of the largest German financial institutions and services providers with assets under management in its subsidiaries of more than €160 billion, and offices in Germany, Luxembourg and Switzerland. DIL is a Luxembourg fund management company of mutual funds known as "fonds common de placement" or "FCPs." Under Luxembourg law, a manager of FCPs has exclusive authority to make investment decisions for the FCPs it manages, and to bring suit to recover any losses incurred by those FCPs. During the Class Period, on behalf of funds it managed, DIL purchased shares of Genzyme common stock, as set forth in the Certification attached hereto as Exhibit A, at artificially inflated prices, and has been damaged thereby. As DIL makes all investments in its own name, and also pursuant to applicable Luxembourg law, DIL has standing to pursue this action for the economic benefit of the funds in which the investments are allocated.

22. Lead Plaintiff the City of Edinburgh Council as Administering Authority of the Lothian Pension Fund ("Lothian") is one of the largest pension funds in the United Kingdom, with over 170 associated employers and a scheme membership of over 67,000, with assets under management valued at roughly £2.865 billion (or $4.42 billion) as of January 31, 2010. During the Class Period, Lothian bought Genzyme common stock, as set forth in the Certification attached hereto as Exhibit B, at artificially inflated prices and has been damaged thereby.

23. Lead Plaintiff the Government of Guam Retirement Fund ("GGRF") provides annuities and other benefits to its members who complete a prescribed number of years in government service, and provides benefits to the surviving spouses and minor children of

deceased employees and retirees. During the Class Period, GGRF bought Genzyme common stock, as set forth in the Certification attached hereto as Exhibit C, at artificially inflated prices and has been damaged thereby.

II. Defendants

24. Defendant Genzyme is a corporation organized and existing under the laws of the Commonwealth of Massachusetts with its principal executive offices located at 500 Kendall Street, Cambridge, Massachusetts 02142. At all relevant times, the Company's shares traded on the NASDAQ stock exchange under the symbol "GENZ."

25. Defendant Henri A. Termeer ("Termeer") was, at all relevant times, Chairman, President, and CEO of Genzyme. During the Class Period, Termeer was a signatory to each of Genzyme's Form 10-Q and Form 10-K filings with the SEC, was quoted in Genzyme's press releases, participated in conference calls with securities and market analysts, and made presentations at industry conferences on behalf of Genzyme. In calendar years 2006-2008, Termeer was paid a total of $50.8 million, or approximately $14 million annually. During the Class Period, Genzyme also paid approximately $74,000 each year for a personal driver for Termeer, and gave Termeer gross-up payments to cover the cost of his (and his wife's and family's) use of Genzyme's corporate jet.

26. Defendant David P. Meeker ("Meeker") was, at all relevant times, Executive Vice President at Genzyme. During the Class Period, he oversaw Genzyme's Therapeutics and Biosurgery business units and Global Corporate Operations. As part of this role, he was responsible for managing Genzyme's Global Manufacturing and Supply, as well as Quality. Meeker participated in conference calls with securities and market analysts during the Class Period.

27. Defendant Michael S. Wyzga ("Wyzga") was, at all relevant times, Genzyme's Chief Financial and Accounting Officer, and Executive Vice President for Finance. During the Class Period, Wyzga was a signatory to the Company's Form 10-K and 10-Q filings and communicated with the market during analyst conference calls during the Class Period.

28. Defendant Alison Lawton ("Lawton") occupied various positions at Genzyme pertaining to regulatory affairs throughout the Class Period, including Head of Regulatory Organization, Senior Vice President of Global Product Access, Quality Systems & Regulatory Affairs, Senior Vice President of Regulatory Affairs and Corporate Quality Systems, and Senior Vice President of Global Product Access, the position she currently holds. Lawton has been responsible for Genzyme's global regulatory activities across a broad range of products. Lawton participated in conference calls with securities and market analysts during the Class Period.

29. Defendant Mark R. Bamforth ("Bamforth") was, at all relevant times, Senior Vice President, Corporate Operations and Pharmaceuticals at Genzyme. During the Class Period, Bamforth was responsible for Genzyme's global manufacturing operations and strategic capacity planning, as well as its Pharmaceuticals business. Bamforth joined Genzyme in 1988. Prior to 2000, Bamforth ran Genzyme's United Kingdom operations. Bamforth participated in conference calls with securities and market analysts during the Class Period.

30. Defendant Geoffrey McDonough ("McDonough") was, at all relevant times, a Senior Vice President at Genzyme. Among his other duties, at all relevant times McDonough headed Genzyme's Personal Genetic Health's business units which encompass the units responsible for Cerezyme, Myozyme, and Fabrazyme. McDonough participated in conference calls with securities and market analysts during the Class Period.

31. Defendants Termeer, Meeker, Wyzga, Lawton, Bamforth, and McDonough are referred to collectively herein as the "Individual Defendants."

32. By virtue of their high-level positions within the Company, the Individual Defendants directly participated in the management of the Company, were directly involved in the day-to-day operations of the Company at the highest levels and were privy to confidential proprietary information concerning the Company, its business, operations, finances, and financial condition. The Individual Defendants were involved in drafting, producing, reviewing, approving and/or disseminating the materially false and misleading statements and information alleged in this Complaint; knew or recklessly disregarded that materially false and misleading statements were being issued regarding the Company; and approved or ratified these statements, in violation of the securities laws.

33. The Individual Defendants, by reason of their status as senior officers of the Company were "controlling persons" within the meaning of Section 20(a) of the Exchange Act and had the power and influence to cause the Company to engage in the unlawful conduct complained of herein. Because of their positions of control, the Individual Defendants were able to and did, directly or indirectly, control the conduct of Genzyme's business and its dissemination of information to the investing public.

FACTUAL BACKGROUND

I. THE NATURE OF GENZYME'S BUSINESS

34. Genzyme was founded as a small start-up in 1981, and has grown into a leading international biotechnology company with revenues of $4.6 billion in 2008. Genzyme's products and services are sold to patients in approximately 100 countries, and are focused on treating rare inherited disorders, kidney disease, orthopedics, transplant and immune disease, and diagnostic testing.

35. Many of Genzyme's products are not traditional pharmaceutical products (which are chemically synthesized), but instead are "biologics," a term describing a range of products created from natural sources – human, animal, or microorganism – and produced through biotechnology methods or other cutting-edge technologies. Biologics tend to be heat sensitive and susceptible to microbial and other contamination, requiring strict adherence to principles of aseptic (sterile) techniques throughout the manufacturing process. To obtain FDA approval to market a biologic, a pharmaceutical manufacturer must file and receive approval for a biologics license application ("BLA").

36. One of Genzyme's most profitable segments during the Class Period was its Genetic Disease Segment, which included drugs to treat a type of condition known as a lysosomal storage disease ("LSD"), *i.e.*, metabolic disorders associated with the absence of certain enzymes. Genzyme's Genetic Disease Segment consisted almost entirely of the drugs Cerezyme, Fabrazyme, and Myozyme (including variants of Myozyme). All three drugs were produced at Genzyme's Allston Landing, Massachusetts facility.

37. During the Class Period, Cerezyme was Genzyme's top revenue-producing product, generating revenues of $1.2 billion in 2008. Cerezyme is currently the only commercially available enzyme replacement therapy treatment for Gaucher disease, the most common of the lysosomal storage diseases.

38. During the Class Period, Fabrazyme was Genzyme's third highest revenue generator, bringing in almost $500 million in 2008. Fabrazyme is a recombinant form of the human enzyme alpha-galactosidase, and in the U.S. is the only commercially available treatment for Fabry disease, which is caused by the lack of or faulty enzymes needed to metabolize lipids and other fat-like substances.

39. At all material times, Myozyme was the third leg of Genzyme's Genetic Disease Segment. Myozyme is the only available treatment for Pompe disease, a rare genetic disorder in which patients lack an enzyme to break down glycogen, which builds up in certain tissues like the heart and muscles and can lead to heart problems, breathing difficulties and muscle weakness. Myozyme was developed in 2005, and most forms of the drug (other than basic 160L Myozyme) have not been approved for commercial sale in the United States, although they are approved for sale in Europe. However, even with its relatively restricted U.S. market, after Myozyme was commercially introduced in 2006 it quickly became the fastest-growing product in Genzyme's history, with sales increasing from $59 million in 2006 to $296 million in 2008. Genzyme's efforts to obtain FDA approval of forms of Myozyme (such as 2000L Myozyme) which could be produced on a much larger scale than basic 160L Myozyme – and which would enable the Company to dramatically expand its lucrative sales of the drug – were therefore of critical importance to investors, and were closely followed by financial analysts.

40. During the Class Period, these three Genzyme products – Cerezyme, Fabrazyme and Myozyme (including Myozyme variants) – benefitted from a lack of significant competition. All three were designated as "orphan" drugs under the Orphan Drug Act of 1983 ("ODA"), which offers financial incentives to induce companies to develop drugs that treat rare disorders or conditions for which there is only a very limited market. These incentives include a guaranteed seven year monopoly on drug sales for the first company to obtain FDA marketing approval of a particular orphan drug. Fabryzyme and Myozyme are both classified as orphan drugs under the ODA, but their orphan status will expire in 2010 and 2013, respectively. Although Cerezyme's orphan drug status expired in 2001, Genzyme continues to hold the patents on it until 2013. During the Class Period, no significant competitor had emerged for any of these

drugs, although, as described more fully below, Genzyme's competitors were poised to fill the void in available products that ultimately arose from Genzyme's contaminated manufacturing processes.

41. Collectively, Cerezyme, Fabrazyme, and Myozyme (despite Myozyme's limited availability) accounted for nearly 50% of Genzyme's total product revenue in 2008. As defendant Wyzga stated in February 2009, Genzyme's Genetic Disease Segment was "our largest segment" and "the biggest contributor to our overall revenue growth."

A. Genzyme's Obligation to Comply With Current Good Manufacturing Practices ("CGMP")

42. As a drug manufacturer, Genzyme was required by the FDA to adhere to CGMP, codified at 21 C.F.R. §§ 210, 211. CGMP regulations require that every manufacturer develop and follow detailed written procedures for all aspects of manufacturing, including standards for buildings and facilities, equipment, laboratory controls, and production and process controls. The regulations also require that each drug manufacturer establish a quality control unit to approve all procedures and recordkeeping policies, and to investigate any errors or deviations from procedure. 21 C.F.R. § 211.22. Pharmaceutical products manufactured in violation of CGMP are deemed to be "adulterated" within the meaning of the Food, Drug, & Cosmetic Act ("FDCA"), 21 U.S.C. § 351(a)(2)(B), and any firm responsible for the manufacture of adulterated product "shall be subject to regulatory action." 21 C.F.R. § 210.1(b).

43. Compliance with CGMP is not only required for existing drug products, but is an essential requirement for the FDA's approval of BLAs. For example, FDA regulations state:

> Approval of a biologics license application or issuance of a biologics license shall constitute a determination that the establishment(s) and the product meet applicable requirements to ensure the continued safety, purity, and potency of such products. Applicable requirements for the maintenance of establishments for

> the manufacture of a product subject to this section shall include but not be limited to the good manufacturing practice requirements.

21 C.F.R. § 601.2. Similarly, the FDA Compliance Program Guidance Manual states that the FDA may approve a new drug application "only if the methods used in, and the facilities and controls used for, the manufacture, processing, packing, and testing of the drug are found adequate to ensure and preserve its identity, strength, quality, and purity." Chapter 46, Program 7346.832, at 4 (effective April 5, 2005).

44. FDA regulations also explicitly make senior company management responsible for ensuring adherence to CGMP. When evaluating controls, FDA inspectors are required to evaluate, among other things, "whether management with executive responsibility ensures that an adequate and effective quality system has been established and maintained." FDA Guide To Inspections Of Quality Systems, at 18.[1] The FDA treats management responsibility for adherence to CGMP as a very serious matter; in fact, when the FDA concludes that management is not providing sufficient oversight of the procedures used in a manufacturing facility, it may impose a requirement that top officers personally sign off on every procedure used in the facility. If the procedures and quality control system systems are not adequate, are ineffective, and/or are not being maintained, then a company's executive management is not upholding its responsibilities under the FDCA.

45. Genzyme was well aware of FDA policy with respect to CGMP. For example, in its Report on Form 10-K for 2007, the Company acknowledged that "[a]ll facilities and manufacturing techniques used for the manufacture of Genzyme's products must comply with applicable FDA regulations governing the production of pharmaceutical products known as

[1] *See* http://www.fda.gov/downloads/ICECI/Inspections/UCM142981.pdf

'Good Manufacturing Practices," and that "[a]s part of product approval, the manufacturer of the product must undergo a pre-approval Good Manufacturing Practices inspection (for a drug or biologic) from the FDA."

46. According to FDA procedures, if an FDA inspector discovers "significant" deviations from CGMP during an inspection, he or she delivers a report on FDA Form 483 to the head of the facility at the conclusion of the inspection. *See* Investigations Operations Manual 2009 § 5.2.3 ("The Form FDA 483 Inspectional Observations is intended for use in notifying the inspected establishment's top management in writing of significant objectionable conditions, relating to products and/or processes, or other violations of the FD&C Act and related Acts which were observed during the inspection.").[2] According to FDA Field Management Directive No. 120, "Inspectional Observations (FDA 483) are of critical importance to both the Agency and regulated industry." Inspectors are instructed that "Observations which are listed should be significant and correlate to regulated products or processes being inspected," and that "Observations of questionable significance should not be listed on the FDA 483." The Directive also requires that copies of each Form 483 be sent to "the top management official of the firm inspected."[3]

47. The company will typically respond to the Form 483 by providing the FDA with a detailed plan to remedy the deficiencies. If the significant deviations from CGMP noted in a Form 483 are not remedied, the FDA may then issue a "warning letter" to the organization. A warning letter is a communication to the firm that has been reviewed within several levels of the FDA, including the district office and FDA headquarters. The letter generally states that the firm

[2] *See* http://www.fda.gov/ICECI/Inspections/IOM/default.htm.

[3] *See* http://www.fda.gov/ICECI/Inspections/FieldManagementDirectives/ucm096015.htm.

has made products that are adulterated, violating the FDCA, and that the firm has a very limited amount of time to address the problem(s) before the FDA takes further regulatory action against the firm, the adulterated product, and responsible individuals. Warning letters are only "issued for significant regulatory violations that require prompt and adequate corrective actions."[4]

B. Genzyme's BLA for 2000L Myozyme (a/k/a Lumizyme), and Its Critical Importance to the Company

48. In April 2006, the FDA approved a biologics license application ("BLA") for the manufacture of Myozyme in Genzyme's Framingham, Massachusetts facility at the 160 liter ("L") bioreactor scale. However, Myozyme dosages are far higher than those for comparable drugs: a single dose of Myozyme is 20 times the size of a dose of Fabrazyme. Thus, producing sufficient quantities requires large-scale production. Prior to the Class Period, Genzyme determined that production at the 160L scale could not produce sufficient quantities of Myozyme to supply the market. Genzyme therefore developed a manufacturing process to permit production on a larger, 2000L bioreactor scale, enabling Genzyme to produce much greater quantities of the drug. Genzyme called its 2000L bioreactor-produced version "Lumizyme" to distinguish it from the original 160L Myozyme. Genzyme was able to obtain quick approval from European authorities to sell Lumizyme in Europe, and began to manufacture Lumizyme predominantly for sale in Europe at its Allston facility. However, because of the differences in the manufacturing process between the 160L scale product and the 2000L product, Genzyme needed to secure a separate FDA approval to sell the 2000L product in the U.S.

49. Ordinarily, when a company seeks approval to sell a new biologic drug, the company files a BLA. The BLA is then thoroughly reviewed by the FDA in an extensive and time-consuming process. If, however, the company only seeks to make a modification to an

[4] *See* http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090279.htm.

existing drug that has already been approved, the company can file a "supplementary BLA" (or "sBLA"), which typically involves a more abbreviated review process.

50. Shortly after obtaining FDA approval in 2006 to sell its basic 160L Myozyme product, Genzyme submitted an application for the approval of Lumizyme in the form of an sBLA to its existing BLA for 160L Myozyme. During the pendency of the Lumizyme sBLA, Genzyme continued to sell Lumizyme in Europe. The Company also began to lay the foundation for a profitable market for Lumizyme in the U.S. by distributing it in limited quantities to adult American patients under a program that permits certain unapproved drugs (typically orphan drugs) to be distributed to patients free of charge prior to FDA approval. As Genzyme explained to financial markets, it intended to transition these non-paying patients into paying ones – and to otherwise expand the paying market for Lumizyme in the U.S. – as soon as it obtained FDA approval of the Lumizyme sBLA.

51. Early response to the Company's limited introduction of Lumizyme in Europe only confirmed the importance of Lumizyme to the Company's ability to generate revenue growth, as sales of 2000L Myozyme (a/k/a Lumizyme) quickly outstripped sales of 160L Myozyme as a treatment for Pompe disease. As defendant Termeer stated on a July 2008 conference call, by mid-2008 approximately ***90%*** of Genzyme's Myozyme-related revenues were attributable to the 2000L product (Lumizyme). Genzyme also developed a process for manufacturing even greater quantities of Myozyme at a 4000L scale, but, during most of the Class Period, the only plant that could manufacture 4000L Myozyme – located in Geel, Belgium – was under construction and/or awaiting approval from European authorities (which eventually occurred in February 2009). Although Genzyme also hoped to eventually gain U.S. approval for the 4000L product, any such approval was years away.

52. Financial analysts and investors considered the Lumizyme sBLA, and the associated expansion of the U.S. market for Myozyme-based drugs, to be of critical importance to the Company. In the words of a financial analyst at Wachovia (as quoted in the February 11, 2009 edition of *The Wall Street Journal*), "at the end of the day, what moves the needle of growth for Genzyme is Myozyme." [5]

C. The Critical Importance of Genzyme's Allston Facility

53. Because of limitations at its Framingham plant, in 2005 Defendants decided to house the Company's Lumizyme production facilities at Genzyme's plant in Allston, Massachusetts.

54. By 2005, the Allston plant was already Genzyme's most important manufacturing facility. Originally constructed in 1994 to produce Cerezyme, in 2002 the Company had expanded the facility to produce Fabrazyme. ***With the transfer of the Company's Lumizyme production facilities to the Allston plant in 2005, by the beginning of the Class Period the Allston plant had effectively become the sole manufacturing site for virtually all of the drugs in Genzyme's highly lucrative and critically important Genetic Diseases Segment.*** In sum, in addition to being the home of Genzyme's Lumizyme production capabilities (and hence the home of what financial markets viewed as "what moves the needle of growth for Genzyme"), the Allston plant – as defendant Termeer noted during a March 2, 2009, conference call – ***also***

[5] Genzyme and market analysts frequently used the term "Myozyme" to refer collectively to all forms of Myozyme, including the 160L, 2000L, and 4000L versions. This Complaint generally uses (a) the term "Myozyme" to refer to all forms of the product; (b) the term "Lumizyme" and "2000L product" to refer to the 2000L-produced form of Myozyme (which was made exclusively at Allston); (c) the term "160L Myozyme" or "160L product" to refer to the 160L-produced form of Myozyme (which was produced at Framingham, Massachusetts); and (d) the term "4000L Myozyme" or "4000L product" to refer to the 4000L-produced form of Myozyme (which was eventually produced in Geel, Belgium).

produced the "world's supply" of both Cerezyme (Genzyme's #1 revenue producing drug) and Fabrazyme (Genzyme's #3 revenue producing drug).[6]

II. THE EXTRAORDINARY, SERIOUS, AND UNDISCLOSED PROBLEMS THAT PLAGUED GENZYME AND ITS FLAGSHIP ALLSTON FACILITY DURING THE CLASS PERIOD

55. Unbeknownst to investors, immediately before and during the Class Period, Genzyme was plagued by a host of extremely severe problems – especially at its critically important Allston facility. These problems not only seriously threatened Genzyme's ability to supply the market with Cerezyme and Fabrazyme, but also jeopardized Genzyme's ability to obtain FDA approval to market Lumizyme, thereby seriously undermining the Company's ability to grow in line with the public expectations that Defendants' own misleading statements had cultivated. These problems (several of which extended beyond just the Allston facility) were the inevitable byproduct of a culture of noncompliance at Genzyme in general and its critical Allston facility in particular. As defendant Termeer belatedly explained to investors after the Class Period, Allston's entire "culture" needed to be changed, because there was "a certain dynamic that takes very significant effort to work out of the plant. There is a human dynamic …"

56. As Defendants were aware, the Allston plant – now more than a decade old, containing equipment that had been produced in the 1980s – was unable to handle the increased burden of manufacturing Lumizyme in addition to Cerezyme and Fabrazyme. As Termeer would also later tell investors "We put too much stress in the plant. We ran it 24 hours a day, over 100% capacity."

[6] During the Class Period, very small amounts of both Myozyme and Fabryzyme were manufactured at the Framingham facility, and, after February 2009, additional amounts of Myozyme were manufactured at the Company's plant in Geel, Belgium. Aldurazyme, another drug in Genzyme's Genetic Disease Segment, was also produced partly outside of Allston, but Aldurazyme production was insignificant in comparison Cerezyme, Fabrazyme and Myozyme (indeed, Genzyme ultimately abandoned commercial activities associated with Aldurazyme).

A. Genzyme's Rampant Violations of CGMP

57. Genzyme's violations of CGMP permeated virtually every aspect of its Allston facility during the Class Period. The discussion below of the more significant of these violations is based on the contents of various FDA documents (including Form 483 reports and warning letters) and statements of certain Confidential Witnesses ("CWs"). As defendant Meeker would later acknowledge at the end of the Class Period – after the FDA had issued two Form 483s and a warning letter in connection with the Allston plant – the host of deficiencies identified by the FDA were "***not new***," and ***were things "we were very aware of and were working to address."***

1. Genzyme's Failure To Implement Necessary Practices and Procedures to Prevent Microbial or Viral Contamination at Allston

58. Throughout the Class Period, and as the FDA would later conclude, Genzyme's Allston plant regularly failed to implement even basic procedures to ensure that its work areas and products were adequately maintained to ensure that its products were sterile.

59. **Deficient Air Flow Sterilization Practices.** Air flow and ventilation is of critical importance to the sterile development and manufacture of drug products because particles and microbes in the air can contaminate the medicine. Among other things, drug companies must control air flow, *i.e.*, they must ensure that air from nonsterile areas does not flow into areas where sterile operations are in process, potentially contaminating them, and they must insure that the heating, ventilating, and air conditioning ("HVAC") system does not itself introduce new contaminants into sterile areas. As Genzyme's own Senior Director of Quality Operations at Allston acknowledged to the FDA during an inspection in 2009, proper airflow testing is a "must."

60. Despite the critical importance of properly sterilized air flow, Genzyme's practices and procedures for testing the sterility of airflow at the Allston facility were inadequate

– and even when its sub par testing showed material deficiencies in the plant's air flow the Company failed to take appropriate follow up or corrective action. For example, as documented in FDA reports and correspondence with Genzyme:

- In April 2006, Genzyme's own internal testing confirmed the existence of ***multiple*** locations within the Allston facility where airflow moved in the ***opposite*** direction from what was required. However, no corrective action was taken.

- In August 2007, Genzyme took some steps to try to validate the HVAC system in one of the "sterile" rooms at Allston where vials of its drug products were filled. However, Genzyme's testing ***failed*** to demonstrate that critical areas – *i.e.*, areas where contamination is likely, such as doorways and other places where contaminants may enter a room – were kept sterile. Moreover, Genzyme's limited testing procedures were inadequate because they failed to include taking samples of the air during testing, and failed to check for proper airflow while employees were engaged in basic manual operations.

- In January 2009, another internal Genzyme evaluation also failed to demonstrate proper air flow.

- Although Genzyme had written procedures requiring air testing in various locations, as a Genzyme Metrology Manager told the FDA during a 2009 inspection, ***no*** documentation existed to establish that any such tests had ever been been performed.

61. **Deficient Cryoshipper Practices.** Genzyme routinely failed to properly use special portable containers, known as "cryoshippers," that maintain biologic material in a frozen state during transport and that play a critical role in the drug manufacturing process. Genzyme used cryoshippers to transport live cells used in the production of its medicines between its facilities in Framingham, Allston, and Belgium. Proper use of cryoshippers was essential to ensuring that Genzyme's raw materials – and thus its end product – remained free of serious contamination and degradation problems. Nonetheless, Genzyme's deficient cryoshipper practices included the following:

- Genzyme's facilities (including Allston) relied on aging cryoshippers that had been produced in 2002 and 2003 and that had a life expectancy of only five years, yet Genzyme continued to use them into 2009.

- Genzyme also never validated the cryoshippers to confirm that they were even working properly, and never performed maintenance on them for the entire time they were in use – even as they continued to be employed well past their 5-year life-expectancy.

- Genzyme frequently utilized the cryoshippers in a manner contrary to their appropriate use as set forth in the operating instructions for the shippers; for example, they would frequently be tipped, which drastically reduced the amount of time that the cryoshippers could maintain their contents (typically live cells) in a frozen state.

62. **Other significant deficiencies in Genzyme's sterilization practices and procedures.** Genzyme committed numerous violations of other, basic anti-contamination practices and procedures. For example:

- As a result of Genzyme's inadequate practices and procedures, Genzyme's Allston employees failed to monitor the amount of microbiological contamination (bacteria, spores, or other organisms) in in-process material and chemical purification agents during the various stages of production.

- Genzyme failed to establish clear procedures for tracking the amount of time that in-process material was "held" in various stages of production, further exacerbating the risk of microbiological contamination or degradation of the material between production stages at the Allston facility.

- Although Allston nominally had internal procedures that required the Company to take action if certain microbiological limits were exceeded either in its in-process material or within the Allston manufacturing facility itself, incredibly, these limits were not based on any sampling that Genzyme had done of microorganisms in the facility, and no testing was ever performed to establish that the limits themselves had been appropriately set.

- As demonstrated by a 2005 evaluation conducted by Genzyme's Allston personnel, the disinfectants used by the plant were inadequate to eliminate a variety of microorganisms, yet Genzyme did nothing to correct this potentially serious problem.

- Genzyme performed tests on various locations at the Allston plant to identify microorganisms, but even when microorganisms were detected, Genzyme's sterilization practices and procedures were sufficiently lacking that they were never able to determine the source of the contamination. Genzyme also failed to maintain documentation to provide any rationale for why it selected particular locations (and not others) for testing.

- The hoses used to deliver liquid drug substances from stainless steel vessels to the filling area at Allston had no filters to prevent contamination by particulates and microorganisms.

- The edges of the observation window overlooking the purportedly sterile filling operations at Allston were not properly sealed in a manner to prevent contamination. According to the Director of Quality, the Production Supervisor, and the Validation Manager at Allston, neither the window nor the walls had ever been tested to determine if they could prevent contamination.

- Personnel wearing sterile protective gear frequently came into contact with personnel who were in street clothes at Allston – a breach of elementary anti-contamination and sterility practices.

- Protective gear worn in the filling suite was never tested for sterility.

- Genzyme kept no records to establish that it sterilized its manufacturing equipment or much of the equipment and tools used during the sterile filling process at Allston.

63. Allston's shoddy manufacturing practices had created problems even prior to the Class Period. One former Allston Distribution Manager, who worked at the plant until mid-2007 ("CW #1"), stated that while he worked there, Allston experienced a virus in early 2007 that required it to shut down the reactors. Other employees at the plant told him this was not the first time Allston had experienced a viral contamination.

2. Allston Failed to Properly Purify its Drugs, Protect Against Particulate Contamination of the Drug Product, and Ensure Quality of the Final Product

64. The FDA's reports and correspondence with Genzyme also identified numerous additional deviations from CGMP that directly threatened the purity and quality of the final drug product.

65. **Deficient Filling Line Practices.** Allston's filling lines, *i.e.*, the machinery used to move empty vials through the process of being filled with drug product, were obsolete and operated in a manner that created a significant risk of contaminating its drug products with metal particles. Among other things:

- The filling lines had been installed in 1994 and had ***never*** been calibrated.

- Metal shavings from the obsolete filling lines contaminated the products.

- Genzyme regularly operated the fill lines at improperly high speeds, causing the lines to jam and necessitating manual intervention. Manual intervention – for which there was a lack of documentation – introduced an additional point of potential contamination.

- Even after the FDA called Genzyme's attention to the improperly high speeds of its fill lines, Genzyme continued to maintain the same speeds and failed to conduct any tests to determine how the speeds affected the final product.

66. **Inadequately Maintained and Contaminant-Producing Chromatograpy Columns.** Allston also experienced serious problems with its "chromatography columns," devices that employed certain chemicals to separate the pure drug product from any impurities:

- The chromatography columns were prone to "rouging," *i.e.*, developing iron deposits (such as rust) that could contaminate the product. According to a Senior Technician who worked at Allston until 2004 ("CW #2") stated that rouging had always been a serious issue at the plant, and Genzyme had no program to combat rouge, even though the problem was sufficiently obvious that sometimes employees could see chips of rouge in the water.

- As FDA inspectors similarly determined in October 2008, Genzyme had ***never*** performed any maintenance on its chromatography columns. Even after Genzyme replied to these serious concerns by promising the FDA that it would belatedly institute maintenance procedures to eliminate rouging, FDA inspectors determined in follow-up inspections that the rouging had continued, that Genzyme had failed to investigate as it had promised, and that it had failed to institute procedures to prevent recurrence of the problem.

- In addition to failing to investigate problems that arose, Genzyme did not institute basic maintenance procedures for the columns, even after the FDA warned the Company about a lack of maintenance on two separate occasions.

- The computer system that calibrated proper chemical substances used by the columns in purification had been improperly programmed since 1999, and had never been updated or even reviewed for errors. As a result, the chemicals used in the columns were not properly formulated to effectively perform the purification.

- Even after the FDA pointed out the programming error to Genzyme in October 2008, Genzyme's subsequent response to the FDA failed to explain how it would ensure that other errors did not exist in the system.

67. **Inadequate Final Product Inspection Procedures.** Genzyme's practices and procedures with respect to conducting visual inspections of its final drug products for particle

contamination, discoloration and/or damage to the vials were also riddled with glaring deficiencies:

- Genzyme frequently received complaints from purchasers or users about foreign particles in Allston's products, but failed to identify the source for all of the particles, and failed to institute corrective measures to reduce the number of contaminations. Moreover, even when drug products were rejected by a buyer for impurities, Genzyme failed to investigate the cause of the contamination.

- As the FDA pointed out, inspections at Genzyme's facilities in Japan regularly spotted contamination in products that the Company's Allston facility had inexplicably approved.

- Genzyme failed to provide appropriate training to personnel responsible for performing necessary visual inspections. For example:

    - Employees conducting product inspections were trained and qualified on products that were different from the ones on which they actually performed the inspections – or had been trained on substances that were not even drug products; and

    - Genzyme failed to train employees on their plant's own latest written inspection procedures.

- The objectivity required to ensure reliable quality control procedures was undermined, in some instances, by having production employees perform visual inspections themselves, instead of having them performed by personnel from the Quality Assurance department (*i.e.*, the department meant to perform oversight functions), thereby violating basic principles of independent quality assurance review.

- Although Allston had set certain limits on the number of drug vials that could be found to be contaminated with particulates before an investigation would be triggered, the Quality Assurance department only considered contaminants detected in a first round of inspections. If a second round of inspections detected additional contaminated vials that caused total contamination levels to exceed established limits, Genzyme would take no action to investigate the problem.

- Even when contamination problems were found in a given product lot, Quality Assurance failed to extend its investigation of contamination beyond the particular contaminated lot to determine if other lots in the same batch, or other products, had experienced similar contamination.

- Genzyme failed to document the amount of time employees at the Allston plant spent on visual inspection shifts. This failure made it impossible to determine whether shifts exceeded maximum time limits, thereby increasing the risk that employee

attention would falter and employees' ability to detect contamination would be materially impaired.

68. **Deficient Particle Contamination Prevention.** In addition to having patently deficient air flow, as described above, Genzyme failed to take other necessary steps at Allston to protect against particle contamination in work areas:

- Genzyme failed to ensure that its Allston employees followed protocols when measuring particles on work surfaces during the performance of various basic filtering procedures.
- Particle measurements were not conducted properly in that they were not taken during routine operations, and were not taken near the sterile filtering apparatus itself, but were instead taken in the middle of the room.
- FDA representatives were able to actually ***see*** particles floating in the air duct; remarkably, however, Genzyme's Quality Unit was not able to answer when the FDA asked whether the particles were being emitted from a sterile area.

69. **Dependence on Outdated Equipment.** Allston's outdated equipment used in various procedures, such as purification, shed metal particles into the facility's final drug products.

70. **Deficient Purification Practices and Procedures.** Genzyme failed to follow critical purification protocols with respect to the manufacturing of Cerezyme at Allston. For example:

- Genzyme reused certain filters employed in the purification of Cerezyme without ever determining whether they could be reused safely, or whether instead they were suited only for single-use.
- Chemicals used in Cerezyme purification were "held" in between production stages without a determination as to whether the hold times were so long as to risk contamination or degradation of the chemicals.

71. The purification and associated procedures for ensuring the integrity and quality of the final products prepared in the Allston plant also suffered from numerous other problems that significantly increased the risk of contamination, including:

- Various chemicals that Genzyme used in the purification process were improperly formulated, and Genzyme did not have effective controls in place to test the chemicals and ensure that they had the proper composition.

- Genzyme failed to rectify this problem even after the FDA alerted Genzyme to the issue in the October 2008 483. Although Genzyme adopted new specifications for the chemicals used in the purification process for Cerezyme, incredibly, it failed to develop procedures or processes to implement the new specifications.

- The Allston plant was plagued by failures to follow procedures for reporting in-process material that deviated from its expected value.

3. Genzyme's Quality Assurance Program Was Wholly Inadequate to Maintain Proper Oversight at Its Overburdened Allston Facility

72. CGMP requires that a manufacturing facility have an independent quality control unit that oversees operations and ensures that production is properly performed. However, the FDA's inspections established that Genzyme's quality assurance program at Allston was in disarray, to the point where activities performed during the manufacturing process were not even authorized by Quality Assurance. As Genzyme's Vice President of Quality Operations would eventually admit to the FDA, Allston had no standard procedure delineating the types of reviews that the quality assurance unit needed to periodically perform. Although quality assurance personnel reviewed specific products, there was no overall assessment as to whether the plant experienced systemic problems, nor were there any efforts to prevent their occurrence.

73. Additionally, Genzyme's quality assurance department did not undertake proper investigations of potential problems, and investigations were regularly dropped before they were concluded:

- As explained above, Quality Assurance did not consider second round inspections when determining whether contamination of a particular product lot exceeded the maximum contamination threshold.

- As explained above, Genzyme failed to institute promised maintenance and investigative procedures after the FDA noted the rouging on the chromotagraphy

columns. Genzyme never conducted any tests to determine whether the rouge had contaminated any of its drugs.

- When Genzyme discovered a microorganism in one of the filling suites in April 2007, it waited six weeks to sterilize the suite, failed to test the product produced in that time to determine whether it had been affected, failed to discover the source of the contamination, and failed to test to determine whether the sterilization efforts had been successful.

- On another occasion in June 2007, Genzyme discovered that metal particles had collected in one of Allston's filters, but failed to determine the source of the particles.

- Quality Assurance personnel failed to audit and evaluate Allston's basic commercial product fill procedures, as well as certain filtration procedures.

- When Quality Assurance monitored certain media fill operations, the design of the window into the filling area made it impossible for them to see parts of the room they were purportedly observing.

- In violation of Allston's written procedures, Quality Control did not investigate when tested material did not meet specifications in May 2008 and April 2009.

- Materials and test results were approved even when tests of samples yielded results outside acceptable ranges, or testing methods did not follow required protocols.

- Procedures for reviewing and approving all documents were not followed.

- No records existed to confirm that Quality Control had reviewed certain air flow testing, despite Allston requirements that the air flow be approved by the quality department.

74. In practice, various steps were taken at Allston to evade Quality Assurance tests and improperly limit the role of the Quality Assurance department in monitoring the manufacturing process:

- In several test runs intended to properly validate the sterile filling process during 2008 and 2009, Allston employees removed specific vials from the filling line for no apparent reason and discarded them before testing could occur – thus making it impossible for the Quality Assurance department to determine if the sterile filling process was in fact functioning properly.

- Genzyme failed to keep records on the number of vials it ran through certain testing procedures that were meant to detect microbiological contamination during the freeze-drying process at Allston.

- Test vials used to detect microbiological contamination during freeze-drying were run through the process too quickly, thus minimizing the chances the test would detect any microorganism growth. Allston's Validation Manager could not explain the reasons for the artificially shortened times for completing that the tests.

4. Mishandling of Raw Materials

75. The FDA also identified numerous distinct deviations from CGMP with respect to practices and procedures at Allston for handling raw materials. For example:

- Raw materials were not properly tested and sampled; required tests were skipped, and employees would test composite samples of materials instead of the individual sample materials themselves.

- Allston did not track failed or sub-standard raw materials, thus making it impossible to determine if any particular supplier posed a systematic risk.

- Allston did not notify all appropriate personnel of raw material failures.

- Inspection requirements for raw materials were not modified in response to raw material failure.

76. Similarly, as CW #2 also confirmed, Genzyme did not keep proper samples on hand of the raw materials it received from other sources, and did not properly test them – a critical defect that impaired Genzyme's ability to identify the source of any problems that later arose.

5. Genzyme Failed to Conduct Proper Training of Critical Allston Personnel

77. The FDA also concluded that Allston suffered from an endemic failure to train its employees in numerous facets of CGMP-compliant production. Among other serious training deficiencies detected by the FDA:

- As discussed above at ¶67, employees regularly performed quality assurance inspections without proper training.

- In violation of Allston procedures requiring recertification, operators on the filling line (a key part of production) often were not requalified for years.

- Although Genzyme had assured the FDA in various BLAs submitted during and prior to the Class Period that certain of its employees would receive "rigorous" training in fill line procedures, FDA inspectors later discovered that Genzyme had ***never*** created ***any*** training program for these employees – rigorous or otherwise. Allston's Microbiology Manager confirmed to the FDA that no such "rigorous" training procedure had ever been documented.

- When employees at Allston failed to follow proper procedures – and, in particular, failed to follow procedures for monitoring microbiological contamination, and procedures for ensuring that chemicals used in the purification process maintained the correct composition – Genzyme did not require the employees to be retrained or counseled, and no record indicated that Genzyme had ever investigated the failure.

78. Indeed, according to a Senior Manufacturing Technician who worked at Allston throughout most of the Class Period before departing in 2009 ("CW#3"), the Company had a habit of hiring people who lacked scientific or biologic backgrounds to work in production and compliance related positions; instead, the Company routinely hired the relatives and friends of current employees and others who, prior to being hired by Genzyme, often had held jobs entirely unrelated to their work at Genzyme, such as auto mechanic or truck driver. CW#3 stated that Genzyme did not want to pay the higher salaries associated with hiring people with the proper level of experience. Genzyme's failure to hire personnel with appropriate backgrounds and training directly conflicted with FDA regulations, which provide:

> Personnel shall have capabilities commensurate with their assigned functions, a thorough understanding of the manufacturing operations which they perform, the necessary training and experience relating to individual products, and adequate information concerning the application of the pertinent provisions of this subchapter to their respective functions. Personnel shall include such professionally trained persons as are necessary to insure the competent performance of all manufacturing processes.

21 C.F.R. § 600.10. *See also* 21 C.F.R. § 211.25.

6. Additional Serious Deficiencies With Allston's Manufacturing Practices

79. **Failure to Perform Routine Vaidation.** Genzyme also failed to perform routine validation of various machines used in the drug manufacturing process. For example, as

explained above, Genzyme ran its fill lines at improperly high speeds without ever validating the effects on drug quality. Genzyme had also refitted the machine used to freeze-dry Allston's drugs in 2003, but failed to ever perform basic tests on its functioning, resulting in errors and deficiencies in the freeze-drying process.

80. **Failure to Update Written SOPs.** Genzyme generally failed to update the Allston facility's written standard operating procedures when procedures were discontinued or altered, such as procedures for visually inspecting vials for contaminants.

81. **Failure to Create or Maintain Adequate Documentation.** Genzyme failed to document and retain records on basic products and procedures at the Allston plant. For example, in addition to other examples given above:

- Allston's basic forms for recording activities performed during manufacturing did not have spaces for certain optional activities, and there were inconsistencies in whether, and how, the performance of such activities was recorded.
- Allston did not keep basic records on the containers and labels of drugs produced by the plant.
- Allston failed to keep proper records of its pure drug substances, *i.e.*, the active ingredients of its medicines. For example, the records failed to record the weight of the components, and failed to record the amount of final drug product these components could be expected to produce. Without these records, Genzyme could not establish or identify warning signals indicating whether too much, or too little, of these substances had been used to create the final product, thus creating a serious risk that the medicine would be improperly formulated.
- Operators did not record the number of vials filled during a filling run, or the number of vials placed in the machine for freeze-drying.
- Quality assurance personnel would remove vials from the freeze-dry process due to quality problems without documenting the removal or the reasons for it.

82. **Problems Not Limited to Allston.** The deficiencies at Genzyme's Allston facility were only further exacerbated by shoddy practices at Genzyme's other facilities. For example, according to a Framingham laboratory technician who worked in the Quality Control

Raw Materials department in 2008 ("CW#4"), Genzyme's Framingham facility was a "hub" of raw materials that were eventually shipped to Allston. But Genzyme's lack of adequate regulatory compliance and other operational deficiencies extended to Framingham as well.

- According to CW#4, Framingham failed to test for air quality and particles, Framingham employees did not wear full-body protective gear to ensure sterility, and persons without protective gear frequently "poked their heads" into the plant's supposedly sterile areas.

- CW#4 also confirmed that a large number of employees at Framingham were college-age and had never received proper training in sterile procedures.

- A Quality Control analyst who also worked at Framingham from early 2007 to mid 2008 (CW#5) reports that Genzyme supervisors instructed that raw material samples be tested multiple times until a result within specifications could be achieved, and that documents evidencing the multiple tests be shredded.

- CW#5 also reports that, in violation of 21 C.F.R. § 211.25(a), instead of receiving a training from "qualified individuals on a continuing basis," laboratory workers were merely told to train themselves, or ask for help if they felt they needed it. CW#5 also states that all records of tests performed for training purposes were discarded in violation of CGMP. Without such records, Genzyme had no evidence that its employees were proficient in their assigned duties, as 21 C.F.R. § 211.25(b) requires; for example, training records would document whether certain employees had difficulty performing delicate laboratory operations and thus could not be deemed proficient at those tasks.

Ultimately, at the end of the Class Period, Genzyme was forced to revamp its quality control procedures at Framingham as well as at Allston.

B. Defendants' Decision to Reduce Production of (and Draw Down Inventories of) Fabrazyme and Cerezyme Further Increased the Financial Risks and Likely Costs Associated With the Serious Compliance Problems at Allston

83. Exacerbating the risks associated with its seriously deficient manufacturing practices, Genzyme was unable to manufacture sufficient quantities of Myozyme without cutting back on the manufacture of Cerezyme and Fabrazyme at the same plant (*i.e.*, at Allston). Without new production runs of Cerezyme and Fabrazyme, Genzyme also began to sell down its inventories of these two drugs, leaving Genzyme vulnerable to shortages if any manufacturing

problems forced new production shutdowns or slowdowns – an eventuality that, given Allston's pervasive deviations from CGMP, was highly likely if not virtually guaranteed. Because Cerezyme and Fabrazyme together represented 41% of Genzyme's product revenue in 2008, Genzyme's decision to deplete its inventories created another enormous undisclosed risk to investors – namely, that the Company would be caught with low inventories of two of its most important products during a period when compliance problems at Allston were so rampant that there was no assurance that production lines for these drugs could be ramped up (and when, to the contrary, conditions were actually already so deteriorated that there was a significant risk that such production lines would have to be shut down or suspended). As Termeer would later admit, "we didn't keep up entirely with the capacity needs of the company to keep the inventories…. The most important thing that a company can do in terms of contingency planning is to make sure you have sufficient inventory to bridge this kind of an interruption."

84. These risks loomed significantly larger (and were made all the more apparent to Defendants) when, in November 2008, Genzyme experienced not one but ***two*** viral contamination outbreaks: first at its Myozyme plant in Geel, and then at Allston. As described further below, these viral outbreaks and related contamination problems had the effect of slowing production in the bioreactors so that sufficient quantities of medicine could not be produced. These contaminations raised the risk even further that Allston would eventually experience additional serious contamination problems during the Class Period that would impede manufacturing and create significant Cerezyme and Fabrazyme shortages. Defendants, however, did not begin to even partially disclose the viral contamination outbreaks, or the depletion of its Cerezyme and Fabrazyme inventories, or the extensive departures from CGMP that plagued the Company's flagship Allston facility, until the latter part of the Class Period.

C. Additional Undisclosed Problems and Risks Arising Out of Genzyme's Rampant Violations of CGMP

85. As a result of Genzyme's undisclosed failure to follow CGMP at its most critical (and most overburdened) facility and its undisclosed failure to manufacture sufficient quantities of its blockbuster products, Genzyme created additional significant risks of which investors were unaware.

86. For example, Genzyme's CGMP deficiencies left it vulnerable to new competitors to an extent far greater than any reasonable investor could have foreseen. Genzyme's business model was built on its ability to supply drugs for diseases that had no alternative treatments, making Genzyme the sole option for those patients. But after Genzyme was forced to halt production at its Allston facility in June 2009 in order to sterilize the plant (as discussed in greater detail below), the FDA (1) urged Genzyme's competitors to rush in-development alternative treatments to market, and (2) granted those competitors special "fast track" status for their applications for FDA approval of those treatments. At the end of the Class Period, Defendants were also forced to admit that as a result of the Company's inability to manufacture sufficient quantities of its leading Genetic Disease Segment drugs, these drugs were in danger of losing their lucrative "orphan" designation.

87. In addition, Genzyme's serious CGMP deficiencies left it vulnerable to a loss of its customer base due to manufacturing shortages. Although Genzyme told investors that its patients would have no reason to switch to whatever alternative treatments did exist, when problems at Allston jeopardized the supply of Cerezyme and Fabrazyme that is exactly what occurred. Indeed, as one analyst commented in the wake of subsequent disclosures about

Genzyme's myriad violations of CGMP, up to ***one-third*** of the Company's Cerezyme patients in the U.S. would change their medications as a result of Genzyme's manufacturing problems.[7]

D. Summary

88. In sum, and as Defendants would later admit, Genzyme's aging Allston plant, with its grossly inadequate practices and procedures and production equipment dating back to the late 1980s, was simply not capable of handling the increased burden of manufacturing Lumizyme in addition to Cerezyme and Fabrazyme. Instead, by the start of the Class Period, the mix of patently deficient practices and procedures, inadequate training, aging and overburdened equipment, combined with increased Myozyme and Lumizyme production demands, was an obvious recipe for disaster that posed serious (but undisclosed) risks for both Genzyme's patients and its investors. ***As Termeer would admit to investors "We put too much stress in the plant. We ran it 24 hours a day, over 100% capacity.***" Similarly, as defendant Meeker admitted at the end of the Class Period – after the FDA had issued two Form 483s and a warning letter in connection with the rampant CGMP violations at the Allston plant – the problems and related issues that had been identified by the FDA were "not new," and were matters that "***we were very aware of*** and were working to address."

89. Moreover, even though Defendants made partial disclosures of the existence of some of these serious problems during the latter part of the Class Period, their partial disclosures were coupled with assurances that the problems had been (or were being) fully and adequately addressed. As further detailed in the section below, however, such assurances were themselves patently false and misleading. Accordingly, Defendants' fraud continued until the last day of the Class Period, when stunned investors learned that the disturbing and unacceptable conditions at

[7] By that time, as a result of Genzyme's manufacturing woes, competitors had fast-tracked alternative treatments and were offering them in early-access or other special programs.

the Company's flagship Allston facility had not only continued to go unremedied, but were even worse than the Defendants had previously disclosed.

III. CLASS PERIOD EVENTS

A. Genzyme Touts the Filing of its sBLA for Lumizyme While Misleading Investors as to the True Condition of Genzyme's Genetic Disease Operations

90. The Class Period begins on October 24, 2007. On that date, Genzyme held a conference call for investors to discuss, among other things, Genzyme's submission of its sBLA for the approval of Myozyme 2000L (*i.e.*, Lumizyme) as a supplement to the approved 160L product produced in Framingham. During the call, defendant Termeer announced that "[t]his month we will file with the FDA the clinical data that they have requested for the approval of the large scale Myozyme manufacturing plant [the Allston plant] and ***we expect the approval to occur in the first quarter of next year***." Touting Myozyme's potential, Termeer noted that once Genzyme obtained approval for the 2000L reactor, it would get a "significant step function of revenues, in the U.S. and in overall Myozyme picture." Genzyme also announced that for the third quarter of 2007, sales of Fabrazyme and Cerezyme had increased 12% and 13%, respectively, from the prior year period, which Genzyme attributed to an increase in patient accruals.

91. Despite the rampant undisclosed deficiencies and severe problems at the Allston plant, in the following weeks and months Defendants continued to tout the "growth potential" of its Genetic Disease/LSD Segment, insisting, among other things, that patients currently taking Cerezyme would have no reason to change to a competing medication. On February 29, 2008, Defendants filed their Annual Report on Form10-K where they stated, among other things, that "All facilities and manufacturing techniques used for the manufacture of Genzyme's products

must comply with applicable FDA regulations governing the production of pharmaceutical products known as 'Good Manufacturing Practices.'"

92. On April 21, 2008, the FDA notified Genzyme that Lumizyme and 160L Myozyme were not sufficiently similar to allow Lumizyme to be treated as a supplement, and instead Lumizyme required its own separate BLA. Genzyme submitted a separate Lumizyme BLA in May 2008.

93. After submitting its separate BLA for Lumizyme in May 2008, Genzyme received a "PDUFA date" of November 29, 2008. "PDUFA," or Prescruption Drug User Fee Act of 1992, permits the FDA to collect fees from applicants, but requires the FDA to set goals for the amount of time it will take to review various types of applications. As a result, the FDA assigns "action" dates to new drug or biologic applications, or "PDUFA dates," which represent target dates for the FDA to issue its determination on a BLA. However, there is no assurance that the FDA will make a determination by any given target PDUFA date, and certainly no assurance that the FDA will actually approve (rather than reject) the new product application by that date. If the FDA needs more time or if the information received from a drug company is unsatisfactory, the date will be extended.

94. Throughout 2008, in conference calls and SEC filings, Defendants repeatedly stated that Lumizyme would be approved by the end of 2008, and that it would be launched commercially in the United States in the first quarter of 2009. Defendants also continued to tout the growth of Genzyme's LSD products and its increasing expansion of its market share. When directly asked by an analyst on a July 23, 2008 conference call whether the FDA would focus more on manufacturing data or clinical data in its examination of the Lumizyme BLA, defendant Termeer stated that the FDA would focus on clinical data, "[b]ecause the manufacturing side of

it is what it is and the products is well characterized [sic] and the clinical data is really what the delay is all about. That makes us feel very good about that moment because we know what the clinical data told us."

B. The Extraordinary Dual Outbreaks of Viral Contamination at Genzyme's Geel and Alston Facilities

95. In September 2008, Genzyme's manufacturing facility in Geel, Belgium, where 4000L Myozyme was manufactured, experienced a viral contamination outbreak. Specifically, the plant was contaminated with the virus strain known as Vesivirus 2117, which is not known to cause human infection but which interferes with the growth of cells used in the manufacturing process. This type of viral contamination is extremely rare, and is known to have occurred at a pharmaceutical manufacturing facility only once before, more than 15 years ago, at a plant run by Boehringer-Ingelhem. Since then, the biologics industry has known very well the degree of control and compliance necessary to avoid the risk of Vesivirus 2117 contamination.

96. Despite the rarity of a Vesivirus 2117 contamination, Genzyme would soon experience ***another*** outbreak of the same viral contamination at its Allston plant just two months later, in November 2008. In contrast, Boehringer's Vesivirus outbreak occurred at only one of its plants – not the multiple production lines in ***two*** plants that Genzyme experienced in September and November 2008.

97. As a result of the Vesivirus 2117 outbreaks, production at both the plant in Geel and the plant in Allston was slowed considerably. Consequently, the Company was forced to (a) write-off millions of dollars of in-process material in Geel (which it falsely told investors was merely part of the ordinary start-up costs of a new plant) and (b) dip into its Lumizyme inventories in Allston – thereby contributing to what the Company merely described as "tight" Myozyme supply in the first half of 2009 ***without*** disclosing the existence of any Vesivirus

contamination or how it had contributed to that "tight" supply. Instead, Defendants failed to disclose the viral outbreaks or their effects on Myozyme supply until June 2009.

C. October 2008: Defendants Receive the Damning October 2008 Form 483, But Fail to Disclose It

98. At around the same time as the viral outbreak at Geel, during September and October 2008 the FDA was conducting inspections of the Allston plant. These inspections identified at least sixteen deviations from CGMP, prompting the FDA to issue a Form 483. Pursuant to FDA Field Management Directive No. 120, this Form was sent to Termeer, as the "the top management official of the firm inspected."

99. The significant problems identified on the October 2008 483 included, *inter alia*, the following:

- failure to monitor the amount of microbiological contamination on in-process material and chemical purification agents during purification;
- rouging on the chromatography column;
- lack of proper maintenance of the chromatography columns "in that they have never been maintained";
- failure to correctly program the column to use the proper chemicals during purification;
- failure to properly test the HVAC system in August 2007, including failure to demonstrate "critical aseptic functions" and to undertake "active viable air sampling";
- failure to properly monitor the composition of chemical agents used for purification;
- operation of Allston's "fill lines" at improperly high speeds, resulting in equipment malfunction;
- failure to use proper forms to record performance of optional activities during manufacturing;
- approval of container closure systems even when validation tests were conducted in a manner inconsistent with the protocol;
- failure to follow internal procedures for reviewing and approving all documents;

- failure to document training or other corrective measures taken when Allston employees deviated from proper procedures;

- use of cryoshippers beyond their life expectancy, failure to perform maintenance on them, and failure even to have properly validated them;

- deficient "master production and control records" on finished drug products that failed to include, *inter alia*, a "description of the drug product containers, closures and packing materials, a specimen or copy of the label and all other labeling, and the signatures and dates entered by the person responsible for the approval of labeling"; and

- deficient master production and control records on drug substances that "do not include an accurate statement of weight of each component" and "do not include a statement of theoretical yield beyond which investigation is required."

100. Genzyme responded to the October 2008 483 on October 31, 2008 with a proposed plan and timeline to address the problems. However, that plan (which, like the October 2008 483 itself, was not disclosed to the public) had a date for resolution of March 31, 2009 – or four months ***after*** the November 29, 2008 PDUFA date. After submitting its remediation plan to the FDA, Genzyme received no communication from the agency informing it that the FDA's concerns had been satisfied. Indeed, defendant Bamforth later admitted that the Company's "first formal response" from the FDA regarding the sufficiency of its proposal came in February 2009, when the FDA issued a Warning Letter that again cited significant violations throughout Allston and confirmed the inadequacy of Genzyme's response to the October 2008 483.

101. Genzyme could not have been surprised to discover that its responses were inadequate. Under ordinary industry and FDA procedures, Genzyme would have been in contact with the FDA after the issuance of the October 2008 483, and would have learned from the agency that the FDA was not satisfied with Genzyme's proposed remedies. Moreover, Genzyme's response to the October 2008 483 was facially inadequate, in large part because Genzyme simply promised to institute new procedures without specifying what those procedures

would be. As the FDA would later state in its Warning Letter to the Company in February 2009, Genzyme's response:

- failed to explain Allston's procedures for tracking the amount of time that in-process material was "held" between production stages;
- failed to explain what procedures Allston would develop for establishing the amount of microbiological contamination that could be detected on in-process material before action would be taken;
- failed to explain how Allston would evaluate whether chemicals used in purification were properly formulated;
- failed to even address issues identified in the October 2008 483 regarding improper training;
- failed to explain whether Allston had continued fill operations in rooms for which proper air flow had not yet been established;
- indicated that Allston had continued to operate the fill line at overly high speeds without evaluating the effect on drug product;
- provided inconsistent responses as to when Genzyme planned to conduct such an evaluation of the lines; and
- failed to indicate whether Genzyme intended to conduct any evaluation and review of the chromatography computer system that the FDA had previously noted contained errors.

102. Similarly, CW#3 confirmed that after the FDA's inspection in the fall of 2008, rather than institute proper training, Genzyme's response was simply to tell employees that they should come to management to request additional training if they felt they needed it. This is precisely how CW#5 described training procedures at Framingham, above at ¶82.

103. Despite the numerous severe deficiencies identified by the FDA in the October 2008 483 and the significant impact they could be expected to have on Genzyme's BLA for Lumizyme – and on Genzyme's ability to continue to operate the Allston plant and maintain production of its most important drugs – Defendants failed to disclose any of this to the public. To the contrary, even after receiving the October 2008 483, Defendants continued to tell

investors to expect that the FDA would approve the Lumizyme BLA in November 2008. For example, when one analyst directly asked during an October 22, 2008 conference call whether anything was "discussed during the closed manufacturing session [of an FDA Advisory Committee meeting] that may affect the approvability of [Lumizyme]," no Defendant made any mention of the contamination in Geel, or of the fact that the FDA had just issued a Form 483 identifying severe deficiencies in manufacturing practices at Allston. Instead, defendant Lawton merely stated: "It was really just a discussion about the biochemical differences that we know exist between the 160 and the 2000-liter," and that the clinical data was the "most important piece." And on the same call defendant Termeer told analysts to expect the Company to earn $4.70 per share in 2009 – a figure that included projected sales from the commercialization of Lumizyme in the United States – and falsely asserted that the Company was in "a very robust position" to meet that figure.

D. As the Allston Plant Becomes Increasingly Overburdened, Defendants Cause Genzyme to Reduce Production of Cerezyme and Fabryzyme and Sell Down Inventories

104. In November 2008, just before the PDUFA date, the Allston facility experienced the ***same*** Vesivirus contamination that occurred at its Geel facility. This second viral outbreak in less then two months slowed production of Lumizyme. As investors would not learn until publication of a *Boston Globe* article on June 25, 2009, this outbreak forced Genzyme to dip into its Lumizyme inventories to continue to supply the market.

105. This second viral contamination outbreak only made more obvious to the Defendants the extent of the endemically poor compliance and ineffective management oversight and controls at Genzyme, and illustrated the kind of disruption that such deficiencies could have on production. The second contamination also highlighted the necessity of manufacturing and

maintaining sufficient inventory to assure continued adequate supply (and revenue-generating sales) through a production slowdown or shutdown. Nonetheless, Genzyme continued to use the Allston plant's capacity for manufacturing Lumizyme while simultaneously (a) reducing Cerezyme and Fabrazyme production; (b) selling down its Cerezyme and Fabrazyme inventory, and (c) continuing to conceal from the market (i) the recurring Vesivirus outbreaks at Genzyme's leading manufacturing facilities, (ii) the other rampant compliance problems at Allston, and (iii) the existence of the October 2008 483 or its contents. Instead, Defendants boasted of growth in demand for Cerezyme and Fabrazyme, and insisted that the FDA would approve Lumizyme by the end of November 2008. And although Defendants told investors that "tight" Myozyme inventories that would limit sales until the Company could secure European approval of 4000L production facilities at Geel, they made no mention of the fact that the short supply was exacerbated by undisclosed contamination problems at Allston.

E. Genzyme's Continuing Reassurances that FDA Approval of the Lumizyme BLA Was Not In Danger

106. In November 2008, a few weeks before the PDUFA date, the FDA informed Genzyme that it viewed certain aspects of its application as a major amendment to the BLA, and was extending the time for FDA review. The FDA also assigned Lumizyme a new PDUFA date of February 28, 2009. Although Genzyme disclosed these developments to investors, Defendants' public statements continued to omit any mention of the viral contaminations, the October 2008 483, or the fact that the Company's own proposed plan to resolve the myriad deficiencies identified by the FDA in the Form 483 had not been approved by the FDA and would not be complete until March 31, 2009 – more than a month after the new PDUFA date. Instead, Genzyme publicly announced that it did not expect the extension of the FDA review to have any effect on its 2009 non-GAAP earnings per share, and confirmed its non-GAAP

earnings guidance of $4.70 per share for 2009 – a figure that included substantial assumed sales of Lumizyme in the United States.

107. On February 4, 2009, Genzyme recalled and destroyed certain Fabrazyme batches because the product did "not meet specification for release-low fill volume, assay below specification." Allston's improper operation of the filling line was one of the specific departures from CGMP that the FDA had identified in the as-yet-undisclosed October 2008 483. Nonetheless, as discussed further below, Defendants continued to conceal the extent to which Genzyme (and notably its flagship Allston facility) failed to comply with even the most basic aspects of CGMP.

108. On February 11, 2009, Genzyme announced its results for the fourth quarter and full year 2008. Once again, Defendants boasted of the market expansion and increasing demand for Cerezyme and Fabrazyme, and defendant McDonough insisted that Lumizyme was "on track" for approval by the new PDUFA date of February 28, 2009. Genzyme's earnings release also projected increased revenues and growth for the Genetic Diseases Segment, including Myozyme revenues between $430-440 million, a figure that included commercial sales of Lumizyme in the United States (which necessarily assumed FDA approval).

109. Although Genzyme also disclosed in its February 2009 earnings announcement that it had incurred expenses from what it described as "incomplete process validation runs" at its 4000L Myozyme plant in Geel, and that Myozyme supply would be "tight" until the Europeans approved the Geel plant, nowhere did Defendants disclose (a) the fact that Genzyme had now experienced ***two*** serious contamination events at its two main Myozyme plants, (b) the contents or existence of the October 2008 Form 483, or (c) any of the other serious compliance problems at Allston. Similarly, Genzyme did not disclose that the "incomplete process

validation runs" were, in fact, the contaminated runs that had slowed Myozyme production as a result of the viral outbreaks in late 2008. To the contrary, when one analyst asked for more information about the "incomplete process validation runs," defendant McDonough falsely brushed them off as an ordinary startup cost of a new plant: "I think the process validation for any new facility does involve runs that are either stopped or abbreviated for a variety of reasons. … So the way to think about that is part of the normal development process that we would undergo for a new facility."

110. On February 23, 2009, Genzyme submitted a supplemental response to the FDA regarding the October 2008 483. At that time, Genzyme still had not received any approval from the FDA regarding its plan for resolution of the deficiencies identified in the October 2008 483, nor had it received any indication from the FDA that Lumizyme approval was possible while the myriad deficiencies at the Allston plant remained outstanding.

111. On February 26, 2009, Genzyme announced that European authorities had approved the 4000L plant in Geel, Belgium, and that it would immediately make the 4000L product commercially available in Europe.

F. The February 2009 Warning Letter

112. During the afternoon of Friday, February 27, 2009, just four days after Genzyme submitted its supplemental response to the October 2008 483, the Company received two more letters from the FDA: a warning letter addressed to Termeer (the "February 2009 Warning Letter") regarding the issues at Allston, and a letter (the "Complete Response" letter) in which the FDA indicated that it would withhold approval of Lumizyme until certain requirements were met, including resolution of the issues identified in the Warning Letter.

113. The FDA's February 2009 Warning Letter stated, in part:

> During the inspection the FDA investigators documented significant deviations from current good manufacturing practice (CGMP) in the manufacture of licensed therapeutic drug products, bulk drug substances, and drug components. These products include Fabrazyme, Cerezyme, and Myozyme. These deviations from CGMP include non-compliance with section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (FD&C Act), the requirements of your biologics license application approved under 351 of the Public Health Service Act (PHS Act), and Title 21, Code of Federal Regulations (21 CFR) Parts 210 and 211.
>
> At the close of the inspection the investigators issued a form FDA 483, Inspectional Observations, which describe a number of significant objectionable conditions relating to your firm's compliance with CGMP….

The Warning Letter then went on to reiterate many of the same observations contained in its earlier October 2008 483 and (as previously described at ¶ 101) also cited the numerous deficiencies in Genzyme's responses to that Form 483. The FDA warned Termeer that the violations discussed in the Warning Letter (and any other significant violations not yet otherwise identified by the FDA) constituted grounds for the FDA to withhold approval of any pending new drug applications (*e.g.*, Lumizyme) that listed the Allston facility as the proposed manufacturing site. It also reminded Termeer that he and Genzyme's management were responsible for assuring that Genzyme was in compliance with the FDCA and all other applicable federal laws and regulations.

114. On March 2, 2009, after the market close, Genzyme issued a press release disclosing the existence of the two FDA letters, and thereafter held a conference call to discuss them. The press release described the Complete Response Letter as "outlin[ing] the remaining items that had to be addressed before the [Lumizyme] application could be approved," and described the February 2009 Warning Letter, as identifying:

> deficiencies related to observations made during an inspection of Genzyme's Allston Landing manufacturing facility performed in September and October 2008. These issues relate to aspects of microbiological monitoring and controls, production equipment maintenance and certain process controls.

The press release was Defendants' first public disclosure of the October 2008 483.

115. Later that same afternoon, Defendants filed the Company's Form 10-K for the year ended December 31, 2008 (the "2008 10-K"), which similarly represented that (1) the February 2009 Warning Letter had identified the same problems that the Company had previously been notified of in the October 2008 483 issued on October 31, 2008, and (2) approval of its pending Lumizyme BLA was dependent on "a satisfactory resolution of the [issues raised in] the FDA's warning letter." On an analyst conference call held that afternoon, defendant McDonough told investors that "in the original 483 there were 16 items listed," and that "[t]hose items are really summarized under four main headings which are contained in the warning letter;" similarly, defendant Lawton noted the overlap between the February 2009 Warning Letter and the October 2008 483, stating that the Warning Letter contained "elaborations on that original 483." On the call, defendant Termeer also conceded that Lumizyme would not be approved on the PDUFA date of February 28, 2009.

116. Although the March 2 press release and subsequent conference call disclosed the existence of the October 2008 483 and that FDA approval of Lumizyme would not occur by February 28 – and although the 2008 10-K noted that the February 2009 Warning Letter had "requested supplemental information in order to fully evaluate the adequacy of our corrective actions" with respect to certain issues raised in that Form 483 – Defendants also made a concerted effort to falsely reassure investors that Genzyme was on track to promptly cure all of the problems that the FDA had flagged and that approval of the pending Lumizyme BLA within a few months was not in danger. As the press release (echoed by similar language in the 2008 10-K) assured investors:

> Genzyme initially responded to the FDA on October 31, 2008, with a detailed plan and timeline to address all of the agency's

> observations. The company provided a progress update on February 23, 2009, confirming that all corrective actions had either been completed or were on schedule to be completed by the original commitment date of March 31, 2009.

117. Similarly, the press release also quoted Termeer stating: "We are confident we will be able to resolve all remaining issues with the FDA within three to six months." It also represented that Genzyme had "readily at hand" all the additional information requested by the FDA, and that Genzyme was "confident that the products produced at the Allston facility continue to meet the highest quality and safety standards." Similarly, on the conference call defendant Lawton assured investors that Genzyme was "confident at this point that we're going to be able to respond in full to the warning letter by the end of this week."

118. Defendants also falsely assured investors that the problems identified by the FDA were not severe enough to require an additional inspection by the FDA. For example, defendant Bamforth analogized the February 2009 Warning Letter concerning the Allston plant to one that Genzyme had received in September 2007 concerning its Lyon, France facility, adding "you'll recall that we had an issue with our Lyon facility and they didn't require an inspection to lift that warning letter."

119. In response to a direct question by an analyst, defendant Bamforth also flatly (and falsely) denied that any of the deficiencies identified in the February 2009 Warning Letter would have an impact on Genzyme's ability to continue to produce the drugs manufactured at Allston – Cerezyme, Fabrazyme, and Myozyme/Lumizyme. Instead, Genzyme's press release noted only that, in the event of a six-month delay in FDA approval of Lumizyme (which was necessary for Genzyme to start ***selling*** Lumizyme domestically), Genzyme's anticipated 2009 non-GAAP earnings would decline roughly $0.12 per share, and its Myozyme revenue (including

Lumizyme) for 2009 would be only $370-380 million, as compared to the previous projection of $430-440 million just weeks earlier.

120. Overall, financial analysts reacted negatively to Defendants' March 2 disclosures. For example, on March 3, JP Morgan issued a report which stated:

> [W]e remain troubled at the lack of disclosure of the Form 483 issuance last fall, since we believe investors would have been more cautious on near-term Myozyme approval if it were clear that the FDA had formally cited the facility for deficiencies as part of its standard review…. Pre-approval inspections in Sep and Oct 2008 resulted in a Form 483, where 16 items were observed under 4 main topics. Rather than making positive strides on resolution of these issues, it is clear that the FDA was unsatisfied with the Genzyme response to the 483 since the agency escalated the issues to a Warning Letter.

121. In response to Defendants' March 2 disclosures, Genzyme shares fell over 6% in after-market trading, falling to $53 from its closing price of $56.52 just hours earlier. The following day (March 3, 2009), after a full day of trading that reflected the broader market's absorption of the prior day's disclosures, Genzyme's shares continued to fall on heavy trading, closing at $52.48 – representing a total decline of $4.04 per share (or more than 7%) from their close on Monday, March 2.

122. Moreover, financial commentators noted that Genzyme had kept news of the FDA letters secret from investors over the immediately preceding weekend, and that it was entirely possible that the earlier 4% decline in Genzyme on Friday, February 27, was attributable to early leakage of the FDA's actions. For example, as reported in *Forbes.com*:

> Genzyme waited three days, including one trading day in which its stock dropped, before disclosing to investors that the [FDA] is delaying a key product.
>
> The Cambridge, Mass.-based biotechnology firm said on a conference call Monday that it had received two letters from the FDA on Friday afternoon.…
>
> But Genzyme did not disclose the existence of the two letters until late Monday, after trading on the Nasdaq had stopped.…

> When Genzyme did disclose the news, it said the delay would lower its 2009 profit by about 12 cents per share. Shares dropped another 5% [sic] in after-market trading.
>
> "One would definitely have thought" the company had a duty to disclose the news earlier, says Geoffrey Porges, a biotechnology analyst at Sanford C. Bernstein. "People do read press releases over the weekend as well," Porges says.
>
> "We needed the opportunity to talk through the feedback with the FDA, and put together our communication," says Lori Gorski, a Genzyme spokeswoman. Gorski declined to say whether the communication with the FDA came before or after the market closed on Friday.

Matthew Herper, "Genzyme Held Bad News as Shares Dropped," *Forbes.com*, Mar. 3, 2009. The *Forbes* article also suggested that news of the FDA's letters had been leaked, given that the Company's share price fell before the news was announced. "Genzyme shares dropped 4% on Friday, followed by another 7% drop on Monday. . . . The drop outpaced the fall of the broader market and of biotech stocks." *Id.*

123. However, Defendants' March 2 disclosures were only partial, and were combined with materially false and misleading assurances that continued to conceal the full truth from investors and the financial community.

124. For example, none of Defendants' March 2 statements disclosed either of the extraordinary viral contamination outbreaks that had infected and impaired Genzyme's production lines at ***two*** separate plants (including its vitally important Allston facility), or the impact that these outbreaks had on Genzyme's drug production. Nor did they disclose the extent to which the true state of affairs at the Allston facility risked exposing investors (and Genyzyme's customers) to further contamination problems and supply disruptions. Similarly, Defendants' assurances that all of the problems that had been identified by the FDA were capable of being remedied within a matter of months, that Genzyme had effective plans for doing

so, and that approval of its much-touted Lumizyme BLA (though delayed) was not at any serious danger of being rejected, were all patently false.

125. Defendants' March 2 disclosures were also materially false and misleading because they failed to disclose that ***Genzyme had recently decided to cancel its plans to manufacture Lumizyme for commercial sale in the United States***. As Termeer later admitted, this decision was due to the seriousness of the compliance issues at the Allston plant, combined with the lack of manufacturing capacity to safely and simultaneously produce reasonable quantities of three drugs (*i.e.*, Lumizyme in addition to Cerezyme and Fabrazyme) at the same plant. Instead, Defendants had decided to continue to seek approval of Lumizyme ***solely*** for the purpose of enabling the Company to then file an sBLA for the 4000L product, which was being manufactured in Belgium but which lacked the required FDA approval for use in the United States. Defendants' undisclosed plans would necessarily cause lengthy delays before any form of "mass-producible" (*i.e.*, 2000L or 4000L) Myozyme could be commercially sold in the United States, because now the Company would have to await ***two*** FDA approvals instead of one. Defendants' failure to disclose its new plans were all the more shocking given that they continued to represent that they intended to market Lumizyme in the United States. For example, as defendant Lawton stated on the March 2 conference call, "Obviously, …we have a complex situation with Myozyme [160L] being approved in the US with the broad label and the fact that it will overlap with some of the indications on the Lumizyme [*i.e.*, the 2000L product produced exclusively at Allston], ***even though we're keeping Lumizyme for the adult population.***" (emphasis added).[8] Defendants also caused the Company to continue to factor in post-FDA-approval sales of Lumizyme in the 2009 revenue guidance that it offered analysts.

[8] Similarly, McDonough said on the same conference call, "So I think the comments here today reflect our ***commitment*** to bring this near-final phase of the 2000 liter approval to its natural conclusion here in the US to

126. In sum, as Defendants knew but failed to publicly disclose, the problems with the Allston facility were sufficiently severe and insurmountable that Genzyme had decided to *abandon* a major source of revenue (from Lumizyme) that it had been telling investors was forthcoming since at least 2007. As Termeer later admitted on December 15, 2009, "***We said [internally, in March 2009] we're no longer going to produce it, because we have an approved plant in Belgium that's dedicated and specializes state-of-the-art [sic] and we must take - we must relieve the Allston plant. . . . And so, it was a very artificial request to get approval for the 2,000-liter because that was a product that was no longer going to be produced***."

127. Accordingly, Defendants' fraud continued, and the price declines experienced by Genzyme shares on March 2 (and February 27) in response to the FDA's February 27 letters would have been much worse but for Defendants' continuing efforts to mislead financial markets.

G. Spring 2009: Defendants' Campaign of False Reassurances Continues

128. On March 11, 2009, in an article titled "FDA Warns Genzyme on Plant Conditions," the *Wall Street Journal* published excerpts of a redacted copy of the February 2009 Warning Letter, which it had obtained from the FDA. In reaction to these further details of the contents of the Warning Letter, on March 11, 2009 Genzyme's stock price dropped $2.37 per share, or 4.3%, to close at $52.82. However, the *Wall Street Journal* (like Defendants' disclosures of March 2) did not disclose any of the facts referenced in ¶ 123-26 above, and stated that defendant Bamforth had (falsely) reassured that "the company has addressed 80% of the problems cited by the FDA and expects to resolve all of the issues by the end of April," and that

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broaden access and fully satisfy the demand for Lumizyme, in this case for US Pompe patients… We continue to feel that Myozyme and Lumizyme will meet their full potential to serve the Pompe community with a corresponding commercial picture similar to that of Cerezyme as we enter this final phase of approvals."

"the Boston plant continues to produce treatments and that 'the efficacy and safety of our products is unchanged.'"

129. In reaction to the new disclosures in the article, and despite Bamforth's reassurances, on March 11, 2009, Genzyme's stock price dropped $2.37 per share, or 4.3%, to close at $52.82. Still, the contamination problems that had been experienced in the Geel and Allston facilities remained undisclosed to investors, as did the full extent and significance of the compliance and related problems at Allston, and the Company's secret internal plans to abandon Lumizyme as a commercial product.

130. On March 24, 2009, Genzyme issued its 2008 Annual Report to shareholders. The report stated: "We anticipate U.S. approval of our Pompe therapy manufactured at the 2,000-Liter bioreactor scale, which we will call Lumizyme, in mid-2000." The Company stated that after Lumizyme approval and approval of the 4000L plant in Geel, "production capacity for our Pompe therapy will allow us to treat patients around the world and support peak revenues of over $1 billion."

131. On April 22, 2009, Genzyme reported its earnings for the first quarter of 2009. Genzyme reported growth in first quarter earnings, but its profit and revenue fell below Wall Street expectations. Whereas in prior quarters Myozyme sales had increased rapidly, in this quarter, Myozyme sales were essentially flat with the prior year period's $67.3 million, and well below the analysts' consensus estimate of $91 million. At this rate, Myozyme revenues would total approximately $270 million for the year, well below the $370-$380 million forecasted in March. The Company attributed the lack of growth to its tight Myozyme supply, but still did not disclose that the supply problems had been exacerbated by contamination in two different plants and continuing manufacturing problems at Allston.

132. Lawton also revealed that although Defendants had told investors on the March 2 conference that no new re-inspection of the Allston facility would be required, the FDA would in fact require a re-inspection. Lawton also admitted that his representation on the prior call that the Lyon facility had not been re-inspected after received a warning letter was false, and that the Lyon facility had in fact been re-inspected. Specifically, when asked by an analyst how long the FDA would take after the re-inspection before it would officially sign off on the Allston plant, Lawton responded, "That varies. I'm just thinking back, for example, our experience with the Lyon facility, I think it was within a couple of weeks of that inspection."

133. In reaction to the disappointing sales figures and news of the re-inspection, the Company's stock price fell 5.6% to close at $51.34 per share on April 22, 2009.

134. Defendants' April 22 disclosures, however, continued to conceal the full nature and extent of the Company's serious compliance and other problems, and were also accompanied by further false and misleading reassurances by Defendants. For example, on April 22 the Company told investors to expect Lumizyme to be approved by the FDA in the second or third quarter, and reaffirmed its prior earnings guidance for 2009. In addition, during the April 22 conference call, defendant Lawton continued to assure investors that the Lumizyme BLA was "on schedule" for approval in the second or third quarter of 2009, stating that "all of the corrective actions for Allston have been completed with the exception of one additional fill study which is unrelated to Lumizyme…. ***So at this point we've actually resolved all of any outstanding items with FDA***. And we are ready to submit our full package which will address all of the items in the FDA complete response letter." As a result of these positive (but patently false and misleading) reassurances as well as Defendants' ongoing failures to disclose the full truth, the fraud continued.

135. On May 6, 2009, Genzyme issued a reassuring press release regarding an analyst day meeting stating that "Genzyme anticipates [the Lumizyme BLA] to be a class 2 resubmission with a six-month PDUFA goal. However, given the ongoing dialogue between Genzyme and the FDA, the company expects that the agency will expedite the review process." At the analyst meeting on that same day, which was attended by defendants Termeer, Wyzga, Lawton, and McDonough, Lawton also repeated that the Company expected the new submission to have a six-month PDUFA date, and added "[b]ut I think what you have seen and what we are very confident in is we've been working really closely with the FDA, and they have clearly been working with us. They've said all along that they're going to work to expedite this approval, so I think we are confident that they are not going to take that full six months, and that approval will be earlier than that."

136. In or about May 2009, the FDA re-inspected the Allston facility to follow-up on the February 2009 Warning Letter issues.

137. On May 8, 2009, Genzyme filed its Report on Form 10-Q for the first quarter of 2009. As the Company had done previously, the 10-Q attributed Genzyme's flat Myozyme sales to tight supply without mentioning its past viral contamination outbreaks, or disclosing the full extent of the problems at Allston, or the utter inadequacies of its purported efforts to seriously and fully redress all of the problems that the FDA had flagged With respect to the February 2009 Warning Letter, the 10-Q again acknowledged that approval of Lumizyme was dependent on resolution of the deficiencies, but reassured that "We believe that we have addressed all the measures required to respond to the FDA warning letter." As on the April 22 conference call and in the press release and analyst meeting of May 6, the Company again told investors that it would have a new PDUFA date that would be within six months, and that the FDA would approve

Lumizyme even before that new date. Again, Defendants failed to disclose the Company's secret internal plans to abandon Lumizyme as a commercial product.

138. On or about May 21, 2009, Genzyme issued a press release which represented that it had submitted the final documentation to address the FDA's outstanding issues regarding Lumizyme, and that it had completed measures required to respond to the February 2009 Warning Letter relating to conditions at the Allston plant. Genzyme also represented that it expected to receive a PDUFA date in November 2009, while adding, in a further effort to reassure investors, that "given the ongoing dialogue between Genzyme and the FDA, the company expects that the agency will expedite the review process." The release also noted that the FDA had begun its Allston re-inspection to confirm that the deficiencies cited in the February 2009 Warning Letter had (as defendants falsely represented) been adequately addressed.

H. June 2009: Allston Suffers Yet Another Serious Viral Contamination Outbreak, And Belatedly Discloses Its Recent History of Other Viral Outbreaks

139. On June 16, 2009, Genzyme announced that it had detected the outbreak of a virus that impairs cell growth in one of six bioreactors at the Allston facility. In the release, Defendants also disclosed for the first time that two earlier outbreaks of this same virus (the Vesivirus 2117) had contaminated, and caused a decline in productivity at, both the Company's Allston and Geel facilities just six and eight months earlier. In other words – even though no other pharmaceutical company had suffered a significant Vesivirus 2117 outbreak in 15 years – Genzyme was now experiencing its ***third*** such outbreak in nine months, and the same virus that had caused shortages of Myozyme in late 2008 was now contributing to a significant shortage of Genzyme's #1 and #3 top revenue-producing products (Cerezyme and Fabrazyme).

140. The June 16, 2009 release also announced that Genzyme would halt all production at the Allston facility, including production of Cerezyme and Fabrazyme, in order to thoroughly sanitize the plant. The halt in production would cause supply constraints in both products and a need for temporary rationing of these highly profitable medicines. For Cerezyme, Genzyme stated that it expected the shortage to begin in August, and to last at least a month. For Fabrazyme, Genzyme stated that it expected the shortage to begin in mid-September, and to last six to eight weeks. As the Company would admit later that month, the shortages were also a direct result of Defendants' decision months earlier to sell down the Company's inventories of Fabrazyme and Cerezyme (while simultaneously reducing its production of these same drugs) in order to squeeze more Myozyme production out of the aging and already overburdened Allston plant. Accordingly, when this third Vesivirus 2117 outbreak struck Genzyme, the Company was left without sufficient Cerezyme and Fabrazyme inventories to last through the shut-down without rationing and cutting sales (and hence revenue).

141. Indeed, Defendants were forced to acknowledge that the viral outbreak and related contamination issues at the Allston facility would hit the Company's bottom line, and promised to provide updated financial guidance as soon as possible. Mornigstar's Karen Andersen estimated that sales of Cerezyme and Fabrazyme could each decline by as much as $150 million, resulting in a 6% hit to the Company's total revenue.

142. Later in the day on June 16, Genzyme held an analyst conference call to discuss the viral outbreak and resulting shutdown of the Allston plant, and confirmed that the entire Allston plant would have to be shut down for weeks during the cleaning process, and that Cerezyme and Fabrazyme supplies would have to be rationed until inventories could be built back up. In addition, Defendants admitted that they had not yet been able to identify the source

of the outbreak, although they suspected that it had entered the plant through raw materials used in production.

143. Nonetheless, in an effort to (falsely) reassure investors, Defendants insisted that the contamination had nothing to do with the general compliance issues identified by the FDA because (Defendants claimed), the FDA had purportedly "signed off" on conditions at the Allston plant after its May 2009 inspection and agreed that the compliance issues there had been satisfactorily resolved. When an analyst asked whether Genzyme had received a formal communication from the FDA confirming that the Allston plant had been found "satisfactory" after being re-inspected, Termeer replied that no formal confirmation had been received, but defendant Lawton hastened to reassure analysts that the compliance issues had indeed been resolved with the FDA. As Lawton represented: "I think, actually, rather than the written communication, to us what's most important is the communication from the inspector and the district office that conducted that inspection to the compliance group at FDA, who then inform the reviewers that everything is resolved and that they can move ahead with approving Lumizyme. And that is what we believe has continued to take place. So I'm not sure whether we and when we will actually get a letter." Defendant Lawton also reassured investors that the recent contamination outbreak would not require another inspection and would not affect the Lumizyme BLA, and that accordingly the Company was still expecting approval by no later than November 2009, and very likely earlier.

144. Each of these statements was materially false or misleading. Defendants' representations to the effect that the FDA's May inspection had resulted in a clean bill of health were simply untrue; to the contrary, as would later be revealed, the FDA concluded that Allston still suffered from numerous severe deficiencies that had not been rectified, and it would demand

an additional re-inspection as a result. Nor was the contamination unrelated to Defendants' compliance issues. The FDA would soon identify Genzyme's handling of raw materials as one of the specific areas in which CGMP was violated in a second Form 483 issued in November; moreover, as described below, on August 14, 2009, defendants Termeer, Meeker, Lawton, and Bamforth would send a private letter to the FDA indicating that both the contamination and the compliance issues stemmed from a single set of "systemic causes" at both its Framingham and Allston facilities, and that it needed to make "fundamental systemic and cultural changes" at both plants.

145. In response to the negative news concerning the disclosure of the viral contamination outbreak and related shutdown at Allston, Genzyme's stock price fell almost $3 per share, from a June 15, 2009 close of $55.62 to $52.75 at the close on June 16 (a drop of nearly 5.5%), on heavy trading of roughly 17 million shares (compared to roughly 6 million the day before).

146. However, the Defendants' disclosures concerning the actual state of conditions at Allston were only partial, and Defendants' continuing reassurances concerning their alleged remediation efforts at Allston and their satisfaction of the conditions that the FDA had identified for approval of the Lumizyme BLA were materially false and misleading, and accordingly the fraud continued. But for Defendants' continuing material omissions and misrepresentations, Genzyme's share price would have fallen even further on June 16.

I. Mid-June to Late October 2009: Additional Partial Disclosures and Continuing False Reassurances

147. On June 24, 2009, Genzyme attended a conference with analysts where it discussed the Allston problems. At the conference, McDonough conceded that the Allston plant had "dropped the ball":

> [T]hat warning-letter experience in Allston was very important for us. It made us recognize that we had lived through a period of unprecedented productivity in that plant with three different products working at a maximal level to meet the demand in the patient community…. I think as Henri [Termeer] put it, we dropped the ball in a time period where we were enormously focused on meeting our obligations to produce these products for patients and, while we did not keep up in an appropriate way with several of the standards that had moved during that period, as they're intended to move, there was no impact on the quality or safety of the products that we were producing. But, it was quite legitimate, I think, for the FDA to note that we were not keeping up appropriately with a moving bar.

Nonetheless, McDonough continued to reassure investors by repeating the Company's earlier assertions that the deficiencies in the February 2009 Warning Letter had been resolved, and that approval of Lumizyme could be expected by November. McDonough even went so far as to assure the assembled analysts that, in any event, resolution of the issues in the February 2009 Warning Letter was unrelated to the Lumizyme BLA, telling them, "[T]he warning letter is unrelated to the approval process for Lumizyme in the U.S. We were specifically made aware of that by the FDA."

148. The next day, Genzyme held another conference with analysts in Cambridge, Massachusetts. Defendant McDonough explained that the Allston plant had originally been built to produce Cerezyme, that Fabrazyme had been added later, and that Myozyme was then rotated in on top of those two drugs. Although not previously disclosed, McDonough also admitted that, after the Allston plant began producing Myozyme, inventory levels of Cerezyme and Fabrazyme declined to low levels because significant capacity that had previously been used to manufacture Cerezyme and Fabrazyme had been allocated to Myozyme. McDonough also admitted that it could take as long as two years for the Company to restore Cerezyme and Fabrazyme inventories to healthy levels.

149. At the same June 25 conference, however, defendant McDonough also continued to provide false assurances to the investment community. For example, he repeated the

Company's prior misrepresentations that (a) the Company had received verbal assurances from the FDA that the Allston plant was in compliance; (b) the compliance issues outlined in the February 2009 Warning Letter were unrelated to the approval of the Lumizyme BLA; (c) re-inspection of the Allston plant was unlikely (and that even if it occurred, the re-inspection was likely to be minor and would not impact the expected approval of Lumizyme in November 2009).

150. Significantly, defendant McDonough also reiterated that it was the Company's intention to market Lumizyme commercially, and stated that immediately after Lumizyme was approved the Company was planning to quickly transition "free" patients (who were currently receiving Lumizyme for free under the FDA's temporary access programs) to full-pay customers.

151. On June 25, 2009, Genzyme issued a press release regarding its progress at Allston. The press release confirmed that the Company had been operating with lower than usual inventories of Cerezyme and Fabrazyme because it had previously allocated significant production capacity at the Allston plant to Myozyme. It also provided an update on the extent of the projected shortages, advising that it expected sales of both Cerezyme and Fabrazyme to be interrupted for six to eight weeks.

152. On July 22, 2009, Genzyme issued a press release reporting its second quarter results for 2009. The press release stated that the recent shutdown of the Allston plant had cut second quarter revenue by $13 million, and would have an even greater impact on Genzyme's business during the second half of 2009. For example, as a result of the shutdown and resulting decrease in its ability to meet product demand, Genzyme (a) sharply lowered its expected total 2009 earnings from $3.52 per share to between $2.35 and $2.90 per share; (b) slashed its full-

year revenue estimates for Cerezyme to between $750 million and $1 billion (from its prior estimate of $1.25 billion to $1.275 billion); and (c) and cut its full year revenue estimates for Fabrazyme to between $510 million and $520 million (from its prior estimate of $560 million to $570 million). The release also disclosed that the Company had decided to discard completed product from the last Cerezyme production run that had been halted in June when the viral contamination outbreak was first detected, that it was still testing remaining material that had been "in-process" during that run to determine whether it could be processed into finished product, and that the outcome of this testing would determine whether the Company would meet the low end or the high end of its revised $750 million to $1 billion guidance for Cerezyme revenue.

153. The July 22 press release also belatedly disclosed what Defendants had secretly decided in March: namely, that Genzyme would transition all Myozyme production to its 4000L Belgium facility in order to provide additional production capacity for Cerezyme and Fabrazyme at the Allston plant, and that it would no longer seek to manufacture Lumizyme (the 2000L version of Myozyme) for commercial sale. Although Genzyme would continue to seek approval of its Lumizyme application from the FDA, the press release advised that it would now do so only as part of a plan to facilitate the filing of an sBLA for the 4000L Myozyme product, which would be filed as an sBLA to the 2000L Lumizyme BLA after the latter received FDA approval. Although Genzyme reiterated that it still expected Lumizyme to be approved by the PDUFA date, set at November 14, 2009, given the abandonment of plans to actually produce Lumizyme, the Defendants' new plan still meant that only the 160L Myozyme (of which the Company could produce very little) would be available for commercial sale in the United States until the second quarter of 2010 at the earliest – far later than the 2009 expectations that the Company had

repeatedly and consistently fostered in the past. As a result, the press release also disclosed that the Company was reducing its global revenue guidance for all types of Myozyme to a range of between $330 million and $340 million (from its prior estimate of $370 million to $380 million). In total, the Company reduced its total 2009 revenue projections to $4.6-$5 billion, from its previous estimate of $5.15-$5.35 billion.

154. That same day, Genzyme held a conference call with analysts to discuss second quarter earnings. Termeer again admitted that the Company no longer intended to manufacture Lumizyme at Allston. Termeer stated that all Myozyme production would be moved out of Allston, and that an additional 4000L reactor would be added to the plant in Geel, Belgium. Termeer stated that the move would "significantly simplify operations in Allston" and admitted that "[w]e need all the reactors in Allston for the production of Cerezyme and Fabrazyme" so that manufacturing Lumizyme at Allston was "not a choice that is available in this case."

155. Later that same day, Defendants held a conference call with analysts to discuss the second quarter earnings release, during which Termeer confirmed that the Company no longer intended to manufacture Lumizyme at Allston, that all Myozyme production would be moved out of Allston, and that an additional 4000L reactor would be added to the plant in Geel, Belgium. Termeer added that the move would "significantly simplify operations in Allston," and that the Company "need[ed] all the reactors in Allston for the production of Cerezyme and Fabrazyme" so that manufacturing Lumizyme at Allston was "not a choice that is available in this case." Even so, Termeer conceded that the Company would not have "comfortable" inventories of Cerezyme and Fabrazyme before 2011, when additional plant capacity would become available. Moreover, defendant McDonough further conceded that even if the FDA approved the pending 2000L Lumizyme BLA by the current PDUFA date in November 2009,

the as-yet-unfiled sBLA for the 4000L product would not be approved by the FDA until at least four months later (meaning that the much anticipated flow of revenue from U.S. sales of a "mass producible" form of Myozyme could also not begin until the second quarter of 2010 at the earliest).

156. On the conference call Defendants also retreated from their earlier representations that they expected the Lumizyme BLA to be approved in fewer than six months, but maintained that they did expect approval in November. As defendant Lawton told an analyst, "So I think as far as the PDUFA date [November 2009], we continue to work closely with the FDA around the Lumizyme BLA, and that has continued, as I have mentioned in the past. I think that we're still hopeful that we can get approval before the PDUFA, but I think that it's more appropriate at this time for us to reset expectations with that date as the goal in mind."

157. Defendants also retreated from earlier claims that there would not be another inspection. Lawton told analysts that "given the routine nature of how they conduct GMP audits, we certainly would anticipate that they would probably want to come out and visit." Lawton also reiterated earlier claims that the Company had remedied the problems in the February 2009 Warning Letter to the FDA's satisfaction. Defendants again stated that they had not discovered the source of the viral contamination, but they continued to believe it had entered the plant through the raw materials.

158. Despite the foregoing batch of unexpected bad news, Defendants' July 22, 2009 disclosures were mixed with reassurances that the Company was putting its past problems behind it and was well-positioned for a full recovery. For example, as defendant McDonough stated, by relieving Allston of the burden of manufacturing Myozyme, the Company was now on the path to creating workable inventory levels again: "[O]ur capacity to supply both Cerezyme and

Fabrazyme in 2010 is materially higher for having pulled Myozyme out of the Allston facility, so we have confidence as we work through this situation in '09 that we set ourselves up well to supply in 2010." Similarly, the Company's July 22 earnings release announced that it had completed the sanitization process at the Allston plant and that the plant would resume production later that month.

159. Market watchers were surprised and disappointed by these disclosures. For example, a July 23, 2009 *Wall Street Journal* article quoted Geoffrey Meachem, a J.P. Morgan analyst, as stating that the Company's revised earnings and revenue projections were "far worse than expected."

160. In response to the July 22, 2009 disclosures, Genzyme's share price dropped sharply to close later that day at $51.21 – a decline of $4.70 per share (or 8.4%) from the prior day's close.

161. Nonetheless, Defendants' disclosures were only partial, and the truth concerning the full extent of the continuing compliance deficiencies at the Allston plant, the utter inadequacy of Genzyme's remediation efforts, and the risk that the pending Lumizyme BLA would likely fail to secure FDA approval all remained concealed. Moreover, the Defendants' continuing reassurances that, in effect, the worst was now behind them and that the Company had turned the corner on its compliance and recurring contamination problems, were all materially false and misleading. Indeed, a number of analysts were persuaded that Genzyme stock had hit bottom and would soon rebound, and accordingly were bullish on the Company. For example, in a July 22, 2009 analyst report, Ian Somaiya of Thomas Weisel Partners reiterated his "overweight" rating on the stock and recommended that "investors get involved once the dust has settled in the coming weeks." Accordingly, Defendants' fraud continued

162. In a letter dated July 27, 2009 (the contents of which were not disclosed until four days later), the FDA notified the Company that a re-inspection of the Allston plant would be required. According to the letter, the re-inspection was required because, contrary to Genzyme's earlier representations, the FDA had determined that the actions that Genzyme had promised to take in response to the February 2009 Warning Letter "ha[d] not yet been fully implemented and some actions [were] inadequate." For example, the FDA pointed out that in response to the February 2009 Warning Letter, Genzyme had promised to institute various maintenance procedures for its chromatography columns, and yet Genzyme had continued to experience rouging on the chromatography columns and had repeatedly failed to investigate the source of the problem. The July 27 letter also pointed out that, as of the conclusion of the FDA's May 2009 inspection, procedures for inspecting and maintaining the columns and training for proper maintenance had not been carried out. The letter also pointed out, *inter alia*, that as of the May inspection Genzyme had still not validated the cryoshippers, contrary to its earlier promises to do so. This letter therefore announced the ***third*** FDA inspection of Allston in less than a year.

163. On July 31, 2009 Genzyme disclosed that it had received a letter from the FDA stating that the agency would be re-inspecting the Allston plant. The Company also noted that the FDA had indicated that the Company had not fully or adequately implemented previously promised actions at the time of the May 2009 inspection, and that it would work with the FDA to schedule a re-inspection as soon as possible.

164. Financial analysts were quick to note that Genzyme's announcement that the FDA would be re-inspecting the Allston plant was a surprise to the market, given Genzyme's previous statements about having satisfied the FDA's concerns during the May inspection. For example, later that same day Jeffries & Co. issued a report stating: "As the Street had assumed the FDA's

successful inspection in May, the agency's notification to re-inspect the facility comes as a surprise, intensifying the complexity associated with manufacturing processes and difficulty in assessing a clear timeline for resolution of issues plaguing GENZ's ERT franchise." Similarly, a report published three days later on August 3 by RBC Equity Research commented that disclosure of the re-inspection "is a new surprise because the company previously stated they had verbal sign-off and believed all issues were resolved. This would add some increased risk to a November PDUFA but timeline is unclear."

165. In response to these disclosures, on July 31, 2009 the price of Genzyme common stock fell to a closing price of $ 51.89, down $4.36 (or roughly 7.75%) from its closing price of $56.25 on the previous trading day, on unusually heavy volume. The price fell an additional $1.51 per share to $50.38 on the next trading day (Monday, August 3) also on unusually high volume, for a two-day decline of $5.87 per share, or approximately 10.4%.

166. Nonetheless, Defendants' disclosures were only partial, and the truth concerning the full extent of the continuing compliance deficiencies at the Allston plant, the utter inadequacy of Genzyme's remediation efforts, and the risk that the pending Lumizyme BLA would likely fail to secure FDA approval all remained concealed. Moreover, Defendants' continuing reassurances to the effect that the worst was now behind them and that the Company had turned the corner on its compliance and recurring contamination problems (including Genzyme's reiteration on July 31, 2009 that it had completed the sanitization of the Allston facility and that production of both Fabrazyme and Cerezyme had resumed following the June 2009 shutdown), were all materially false and misleading. Accordingly, Defendants' fraud continued.

167. On August 10, 2009, Genzyme filed its Form 10-Q for the second quarter. The 10-Q discussed the contamination at Allston and stated: "We believe the virus was likely introduced through a raw material used in the manufacturing process." The 10-Q reiterated that "At the end of July 2009, the FDA informed us that it will re-inspect our Allston facility to verify that all corrective and preventative actions identified in the February Warning Letter have been implemented. The FDA indicated that all promised actions had not been either fully or adequately implemented at the time of the May inspection, such as identifying measures to prevent column rouging; inspection and preventative maintenance, or PM, of remaining chromatography columns; revision of PM scheduled inspection to every six months for Chromaflow columns and an annual inspection for all other column types; revision of column packing records to include internal inspection; development of on the job training for preventative maintenance and division of maintenance responsibility; and implementation of the revised transfer/transport procedures for cryoshippers."

168. The second quarter 2009 Form 10-Q also provided updated guidance on the impact that the June 2009 viral contamination outbreak would have on Cerezyme and Fabrazyme supply, and on the Company's earnings. Although the Company's forecast regarding the period of supply constraint (and earnings) for Fabrazyme was unchanged, the situation with Cerezyme had deteriorated. In particular, Genzyme announced that it had decided to discard approximately 80% of the "in-process" material that was unfinished when the Company shut down production at the Allston plant in June, and that it was still evaluating how to handle the remainder. The destruction of the in-process Cerezyme materials required a further write-off of approximately $8.4 million (in addition to $14.2 million previously reported), and the Company had to reduce its second quarter earnings accordingly. Defendants also admitted that Genzyme's inability to

supply its drugs created a risk that they would lose their special orphan drug status. As a result, the Cerezyme shortfall, originally projected to end in October, would continue through the end of 2009. Genzyme also adjusted its total Cerezyme revenue forecast for 2009 to $750 million (the low end of the range announced on July 22).

169. In the days that followed, in light of the Cerezyme shortage that was more severe than originally projected, the Company and U.S. and European regulators issued revised guidelines for allocating the existing Cerezyme supply among patients. For example, on August 14, 2009, the EMEA issued guidance recommending that (a) only patients with the greatest need for Cerezyme (namely infants, children and adolescents, and adults with severe, life-threatening disease progression) should continue to receive treatment; (b) even these "greatest need" patients should take Cerezyme at a lower dosage to conserve limited supplies; and (c) adult patients without severe, life-threatening disease progression should suspend treatment or switch to miglustat, an oral therapy for adults with mild to moderate type 1 Gaucher disease.

170. On August 14, 2009, defendants Termeer, Meeker, Lawton and Bamforth privately wrote to the FDA to try to address the agency's continuing concerns which, according to the letter, included not only Allston but also Framingham, *i.e.*, the hub for raw materials. Defendants' confidential letter stated: "We also understand that the FDA's observations are only representative and we are therefore taking an approach that will address the individual observations ***and the underlying systemic causes***. ***We plan to make fundamental systemic and cultural changes to our operations as appropriate***." With respect to the viral contamination outbreak at Allston, Defendants implicitly acknowledged that the outbreak was related to the Company's compliance issues, stating: ***"We recognize [] that the viral investigation and Allston Landing restart must be completed in the context of the broader compliance remediation***

activities." Defendants' private letter represented that Allston's new procedures to address corrective and preventive action ("CAPA") would "focus[] on prevention of viral contaminations in the future. The program will build robust viral barriers around the process, particularly with respect to the treatment of raw materials…. Finally, we are focusing on identifying and implementing facility improvements around air flow, people flows, and waste streams that will provide improved containment should a future viral contamination be detected."

171. In this undisclosed letter, the Defendants also represented that Genzyme "is developing a broad based and comprehensive approach to remediation, with particular focus on Framingham and Allston Landing." According to their letter, as part of such an approach Genzyme would develop additional controls at both plants, including additional evaluation of environmental monitoring, additional experienced supervision over laboratory operations, and additional oversight and quality checks. In sum, although Defendants' private August 14, 2009 letter to the FDA effectively admitted that Defendants had ***never*** remedied the problems that had been expressly identified by the FDA in the fall of 2008 and reported in the FDA's October 2008 483, Defendants were never so candid with the financial community, and indeed continued to conceal the truth from investors.

172. On August 31, 2009, Genzyme publicly disclosed (a) that the EMEA had completed an inspection of Allston; (b) that the inspection had identified one "major" deficiency and several lesser ones; and (c) that the Company would respond to the EMEA regulators within fifteen days. In light of Defendants' comments as recently as July 31 that the sanitization process at Allston had been completed and other past reassurances, analysts were surprised by and responded negatively to the news that another regulator had found additional problems. For example, analyst Christopher Raymond of Robert W. Baird, Inc., expressed surprise that there

were "still significant deficiencies at Allston this late in the game," and noted that the "odds of continued delays at Allston Landing and longer-lasting fallout from said delays are now higher." This analyst report also provided some context, noting that historically, less than 10% of EMEA observations on inspections have been classified as "major."

173. On September 21, 2009, *The Boston Globe* published an article on the most recent viral contamination outbreak at Allston. As that article observed, "[s]ome industry watchers and patients fault Genzyme for not having enough drug inventory on hand to keep patients from missing doses… Adding Myozyme production in Allston contributed to the inventory shortage by taking up space that could have been devoted to making the other two products. In the previous cases when viral contamination occurred, Genzyme had enough drugs stored for patients." Two weeks later, defendant Termeer would admit as much in an October 15, 2009 article in *The Wall Street Journal*, which quoted Termeer as stating: "We should have had the inventory." The same *WSJ* article also reported that, by one analyst's estimate, "one-third of Cerezyme patients in the U.S. may switch therapies because of Genzyme's manufacturing woes."

174. On September 23, 2009, Genzyme issued an update on its progress in restoring supplies of Cerezyme and Fabrazyme. The Company reported that all six bioreactors at the Allston plant were fully operational, and that newly produced Cerezyme would be available for shipment in November and December. For Fabrazyme, however, Genzyme disclosed that renewed production was delayed, that new shipments were not expected until mid-December, and that new conservation/rationing measures to ensure adequate supply would be advisable until the new Cerezyme shipments became available. Accordingly, the Company disclosed that it was

reducing its estimated total 2009 revenue from Fabrazyme by another $60 to $70 million, from the range of $510-$520 million to only $450 million.

175. At the UBS Global Life Sciences conference that same day, defendant Termeer admitted to analysts:

> The reason we were short of capacity was that we didn't keep up entirely with the capacity needs of the company to keep the inventories and the biggest culprit here is Myozyme…. The most important thing that a company can do in terms of contingency planning is to make sure you have sufficient inventory to bridge this kind of an interruption.

176. The financial impact of the June 2009 viral contamination outbreak and the resulting shutdown of the Allston plant was further revealed when Genzyme released its third quarter results on October 21, 2009 and reported that its revenue for the quarter had dropped $100 million (or roughly 9%), from $1.16 billion in 2008 to $1.06 billion in 2009. Of particular note, Cerezyme revenues dropped sharply to $93.6 million, compared to $309.3 million in the prior year period, and Fabrazyme revenues fell to $115.2 million, compared to $125.6 million in the prior year period. Even worse, the Company also reported that its third quarter GAAP net income had plummeted more than 85%, from $119.6 million in 2008 to a mere $16 million in 2009. In addition, after taking into account the costs of remediating the Allston plant and the write-offs taken on Cerezyme material that had to be discarded, the Company announced it was reducing its estimate of full year EPS for 2009 to only $2.26, down from its previous estimate of $2.35-$2.90. The Company's October 21, 2009 earnings release also informed the market that the FDA was currently in the midst of its previously announced re-inspection of the Allston plant.

177. However, the Company's October 21, 2009 press release also continued to reassure investors concerning the thoroughness of the steps it had taken to address compliance issues. For example, the press release reported on several steps taken to strengthen its

manufacturing operations, including appointing a new site leader at Allston and hiring third-party quality assurance and compliance experts to review the Company's operations. In addition, in the press release (and in the Company's conference call held later that day, as well as in the Company's third quart 2009 Form 10-Q filed on November 2, 2009), Defendants continued to reassure investors that Lumizyme would be approved by its November 2009 PDUFA date

J. The Truth Concerning the Total and Utter Inadequacy of Genzyme's Purported Remediation Efforts Is Finally Revealed

178. Despite its best efforts to convey the impression to the investing public that it had implemented all steps necessary to cure all of the FDA's prior concerns about its manufacturing processes and compliance with CGMP, by mid-November 2009 the Company could no longer hide the fact that it had ***never*** come ***even close*** to getting its house in order.

179. On Friday, November 13, 2009, the last day of the Class Period – and the day before the Lumizyme BLA PDUFA date, when Defendants had assured the market that they would receive FA approval – two extraordinary events occurred.

180. First, on that date, Genzyme and the FDA issued a public notice directed to health care providers to warn them that the Company was experiencing another significant contamination episode, and that it had discovered vials of Cerezyme, Fabrazyme, Myozyme, and Thyrogen (a diagnostic agent used by thyroid cancer patients) that were contaminated with foreign particles including fragments of steel and non-latex rubber, as well as fiber-like materials from the manufacturing process. The FDA warned that ingesting the particles could have serious adverse health effects, including allergic reactions and blood clotting.

181. The extraordinary revelation that the Company had discovered medicine produced at the Allston plant that was contaminated by multiple different foreign substances effectively disclosed the true depth and pervasiveness of the compliance issues at Allston, and decisively

dispelled Defendants' false assurances that FDA approval of the Lumizyme BLA was possible in the near term, let alone by its PDUFA date one day later. For example, as an RBC Capital Markets' analyst concluded on November 13, the contamination warning to healthcare professionals showed that (i) "Genzyme is not ready" for approval of the Lumizyme BLA, (ii) "the Allston plant is not yet in the clear," and therefore (iii) there was also "further risk to Cerezyme estimates" (inasmuch as Cerezyme was also produced at Allston). The *New York Times* reported on November 14, 2009, "One outcome of Friday's news is that approval of a new Genzyme drug, Lumizyme, is likely to be delayed beyond Saturday, which is the F.D.A.'s decision date. The company has said that Lumizyme would not be approved until manufacturing problems at the factory were resolved. But the F.D.A. said Friday that it was still inspecting the factory." Dow Jones News Service reported on November 13, "[T]he news is the latest misstep for a company trying to clean up a series of manufacturing problems at its Allston, Mass., plant and reassure investors and the FDA of its progress. This latest contamination threatens to derail those efforts as Genzyme awaits a key FDA decision – expected to come by Saturday – on a version of Pompe-disease treatment Myozyme, called Lumizyme."

182. The market thus correctly concluded that the Company's critically important BLA for Lumizyme – which was essential to Defendants' stated plans to use an approved Lumizyme BLA as the foundation for thereafter obtaining approval of an sBLA for "mass-producible" 4000L Myozyme – was now facing near-certain rejection.

183. Indeed, also on November 13, 2009, Defendants' received a ***second*** Form 483 for Allston, as well as a second complete response letter concerning the Company's pending Lumizyme BLA (the "November 2009 Complete Response Letter"). On that same day, the FDA sent a complete response letter rejecting Genzyme's BLA for Lumizyme.

184. The 22-page November 2009 483 was addressed to defendant Termeer, and listed a virtually unprecedented ***49*** separate instances of significant CGMP violations observed by inspectors at the Allston facility during the inspection that FDA personnel conducted between October 8, 2009 and the date of the letter. These violations included:

- the lack of any "established standard operating procedure to describe the periodic review and the contents of the review, of deviations and investigations performed by the Quality Unit. The Quality Unit performs individual reviews and approval. However, there is no overall assessment of the deviations and investigations with respect to their impact on the manufacturing operations and Quality Controls to prevent their reocurrence."

- failure to calibrate the filling line, which had been installed in 1994, for "line speed, stopper bowl speed, or volumetric control"

- failure to investigate when a returned drug product implicated potential problems in associated product batches

- failure to validate the sterilized filling process (due, as described above, to employees removing vials from the line before they could be tested for contamination)

- failure to train and qualify employees

- failure to maintain records of tests for microbiological contamination and improper air flow

- failure to maintain records of equipment sterilization

- failure to properly test for and investigate instances of potential microbiological or particle contamination

- failure to properly handle raw materials

- failure to update written standard operating procedures

- failure to investigate instances of in-process material that tested outside expected ranges

- use of disinfectants that could not eliminate certain sources of biological contamination

- use of an improper building design and personnel flow that promoted contamination, as confirmed by Genzyme's Associate Director of Quality Control Microbiology and its Senior Manager of Fill Finish Operations

185. In addition, the November 2009 483 contained numerous other observations confirming that Genzyme had failed to adequately clean and decontaminate the Allston facility even after the second Vesivirus contamination outbreak in June 2009. For example, the November 2009 cited Genzyme for (a) failing to ensure that the decontamination vapor reached all of the relevant areas, (b) failing to justify the placement of the biological indicators used to test for the success of the decontamination, and (c) failing to follow up on locations where it was determined that decontamination had been ineffective. Perhaps even more damning, the November 2009 483 also flagged Genzyme for failing to implement the changes it had promised after it received the *October 2008 483* (which was now more than a year old). For example, although Genzyme had adopted new specifications for the chemicals used in the purification process for Cerezyme, the November 2009 483 observed that the Company had failed to developed any procedures or processes to implement them.

186. The November 2009 483 also made a number of other telling observations about the Company's failure to adequately prevent contamination by metal particles. In this regard, it stated:

> Investigations into metal particle contamination in finished drug product concluded equipment used in the aseptic fill process sheds metal particulates into vials before drug product is filled based on the equipment design and intended use. The equipment is used for filling of Myozyme, Fabrazyme, Cerezyme, and Thyrogen. Your follow up to this conclusion is inadequate because it fails to address prevention contamination before long term corrective actions are implemented in 2010 and 2011.

187. As Genzyme reported in a press release issued after the end of the Class Period on November 16, 2009, in the complete response letter, the FDA stated that it declined to approve Lumizyme, citing deficiencies at a manufacturing plant and that satisfactory resolution of the deficiencies at Allston was required before the Lumizyme application could be approved

188. In response to the stunning disclosures of November 13, 2009, as well as the market's immediate recognition that the new contamination issues doomed the Lumizyme BLA, the price of Genzyme's stock closed sharply lower at $49.28, compared to its closing price of $53.17 on November 12, reflecting a one day drop of $3.89 (or roughly 7.3%) on unusually heavy trading volume of 28 million shares.

IV. POST-CLASS PERIOD EVENTS

A. Defendants' Post-Class Period Admissions

189. On November 16, 2009, Genzyme issued a press release formally announcing that it had received the November 2009 483 and Complete Response Letter. The press release disclosed that these FDA communications had informed Genzyme that the FDA had identified numerous unremediated compliance deficiencies at the Allston plant, and that the Lumizyme BLA would not be approved until the compliance issues had been resolved.

190. In a tacit but belated admission that its practices and procedures had been, until then, woefully deficient, Genzyme's press release told the market that it planned to address the deficiencies by, among other things, (a) establishing additional internal controls, (b) updating the Allston plant's fill/finish capabilities (*i.e.*, its capabilities for putting drugs into vials ("fill") and then sealing and labeling them ("finish")), (c) transferring additional filling activities to existing Genzyme contract manufacturers, and (d) utilizing excess capacity at Genzyme's Waterford, Ireland facility.

191. On that same date, Genzyme also held a conference call to discuss the November 2009 483 and Complete Response Letter. During that call, Defendants announced that the Allston facility would once again have to temporarily shut down while the Company sought to address its continuing and serious compliance deficiencies. Additionally, defendant Termeer

admitted that the problems at Allston could be traced directly back to 2006, when the Company overburdened the Allston plant by adding Myozyme production lines there on top of the existing Cerezyme and Fabrazyme lines. As Termeer explained:

> We actually -- the introduction of the production of Myozyme in Allston was a very significant factor in the complications that we have experienced there.
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> ***
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> ***We can explain in a very clear way why and how it came that we overloaded the Allston facility with too much to do and then creating these difficulties. And the main reason, of course, was that we introduced Myozyme into that prior to the completion of the facility in Belgium.*** Myozyme, of course, treats also an extremely severe disease, and the need for the product was very, very clear to us. And it absorbed – as we introduced it, it absorbed any disparate capacity that we had available, or spare inventory that we had available for Cerezyme and Fabrazyme. And that created a problem of not having the back up in terms of inventory at the time that the fires hit, and that is the prime cause for the economic impact of this interruption. This clearly can never happen again.

192. During the call, Defendants also repeatedly acknowledged that the serious deficiencies identified in the just-received November 2009 483 were the ***same*** problems that had plagued the Company for years, and that they had been fully aware of them. For example, Defendants admitted that many of the problems were traceable to the fact that the Allston facility had been using older and outdated equipment. As Meeker stated:

> [W]e do have a very specific issue at our Allston plant, which is related to the nature of the particulate matter, and that has to do with the age of the equipment. So specifically, the metal-on-metal contact, and that was, I think, part of what was highlighted in the FDA concern around the metallic particles.
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> So I think the issue of the inspection, the particulates are certainly part of it, but they're [the FDA] looking at the fill/finish suite as a whole, and as I indicated earlier that is an older piece of equipment and so there was a number of issues there that they highlighted and -- ***many of which we were very aware of and were working to address,*** that we will continue to address.
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> ***

> [T]he other observations [pertaining to production rather than fill/finish] were mainly related -- or, to give you an example of the kinds of things, were related to the documentation, for example, of different things that are performed in the plant, the training that might be surrounded to that. ***And these were elements that we obviously knew about, knew that we needed to continue to improve***, and in fact had developed a comprehensive plan and had submitted that plan to the FDA in advance of their inspection as part of our overall remediation effort.

193. Similarly, when one analyst asked whether certain observations in the November 2009 483 pertaining to the "fill/finish" areas of Allston were new, Meeker admitted that they were ***not*** new, stating:

> ***[N]othing has changed.*** I think we know, and fill/finish has been an area of focus and needs some inspection, and again it reflects the age of the equipment so we understand those issues and the observations. And so, as I said, ***much of what was highlighted are things that we understood and were working towards***. There were some new observations, but maybe the new observations I would put in the context of a five-week inspection of just an intense focus on this area. So again, ***I'm not surprised that there were some additional observations, but the fact that we needed to continue to work on fill/finish was not new.***

194. Defendant Termeer also agreed that many of the problems were traceable to Allston's obsolete equipment, telling analysts, "So the remediation plan here really is to get the … the limitations that be the equipment provides [sic]. This is 1994 installed equipment, probably produced in the late 1980s. And it is clearly -- when you look at the new technologies that have become available, it is more difficult to operate this technology."

195. Recognizing that Genzyme had a history of telling the market that all problems had been resolved when they had not been, one analyst asked:

> [I]t seems like we have known about these requirements now for several months. And it always seems that it is going to get resolved, yet it pops up again. So maybe just help us understand a little bit what does it take to actually getting those resolved?

Acknowledging that the problems at Allston were also indicative of quality problems across the Company and represented systems failures rather than isolated incidents, defendant Meeker responded:

> [W]e have employed a third-party consultant, the [Quantic] organization, who are specialists in the whole area of quality remediation, and it is with them we have worked closely to develop this comprehensive plan.… And that has to do with every aspect of quality, if you will, both in terms of revisiting the standards that we have, improving the overall – the corporate views of not just site-specific, but these cut across the whole corporate operations function, the training that goes along with that, of course.

196. On December 3, 2009, Genzyme announced that it had abandoned the Lumizyme BLA, and that it would submit a new BLA for the 4000L product rather than seek to have the 4000L product approved as a supplement to the Lumizyme BLA. Credit Suisse issued a report stating that "the decision to abandon 2,000L approval could signal that the manufacturing deficiencies at Allston could take longer to resolve."

197. In a *mea culpa* letter to shareholders from Genzyme, filed with the SEC on Form 8-K on December 10, 2009 and signed by defendant Termeer and the Company's Lead Independent Director, Robert J. Carpenter, the Company admitted that it had "learned some important lessons." The letter further stated that Genzyme was now "acting decisively" to improve manufacturing, quality and regulatory operations:

> We have learned some important lessons and are acting decisively to improve our manufacturing, quality and regulatory operations. Importantly, we are aggressively taking a proactive approach to risk management. . . Our goal is to restore Allston to world-class standards and establish best practices throughout Genzyme's global manufacturing organization. This effort has the highest level of management attention. Working with a leading quality assurance advisory firm, we developed a comprehensive strategy and two-year plan that will significantly lower the probability of another setback. We are implementing the plan with a sense of urgency and are making progress every day.

198. In the same letter, Genzyme stated that it had moved all Myozyme production to its Belgium facility, and was removing its fill/finish capabilities from Allston and expanding its fill/finish capabilities at its Waterford, Ireland facility.

199. At the December 15, 2009 "DB Biotech Boston Confab," Termeer also admitted that the Company had determined back in March 2009, after the issuance of the February 2009

Warning Letter, that it would ***not*** produce Lumizyme at Allston, and that instead it would only commercially market the 4000L material produced in Belgium. The marketing of the 4000L product, however, under that plan would have required FDA approval of a subsequent sBLA after approval of the Lumizyme BLA -- meaning that Genzyme had known since at least March 2009 that it would not be in a position to sell any form of "mass-produced" Myozyme in the United States in 2009. In other words, Termeer admitted that for several months in 2009, the Company had intentionally misled investors as to its plans for Lumizyme and the expected revenues from its sale that year. As Termeer explained on December 15, 2009:

> [T]he FDA evaluated all the characteristics of the 4,000 liter that we had filed. ***We filed with this the FDA [sic] shortly after the warning letter and it will be response to that in February, because it was then that we decided in March we will pull Myozyme out of Allston altogether. We said we're no longer going to produce it, because we have an approved plant in Belgium that's dedicated and specializes state-of-the-art and we must take - we must relieve the Allston plant.*** So we told the FDA that then and as we asked about that, they – we talked about the hundreds of patients in this country that are in treatment already with Myozyme, and they needed to be changed over to the 4,000 liter material. So to do that, we needed to change the IND, which was the basis for these patients to be treated free of charge and we filed with the FDA all the characteristics for the 4000 liter earlier this year. The FDA then also went to Belgium looked at the plant, they went to Ireland to look at that plant for some time and those were very constructive inspections, and gave us the permission to change all the patients in the United States. ***And so, it was a very artificial request to get approval for the 2,000-liter because that was a product that was no longer going to be produced and everybody knew about this. So that's how it went.***

200. Defendant Termeer also acknowledged the severity of the Allston problems, saying, "[a]nd if the FDA is not happy with how we respond to that particular inspection and those observations or in any way thinks that [it is a] stronger warning signal then that ***could lead to [a] consent decree***."

201. Termeer also finally admitted that the aging Allston plant had been operating beyond its capacity following the addition of Myozyme to the plant's production lines, and that

the Company had also knowingly reduced its inventories of Cerezyme and Fabrazyme without replenishing them to make room for Myozyme production at the plant:

> We've put too much stress in the plant…. We had some capacity available in Allston and we put it [Lumizyme] in Allston to utilize that capacity. The product became approved in Europe immediately, two and a half years ago, and throughout the world, except United States, 45 countries approved that product for 2011 product. And it then took off, and it is of course an enormously high dose, 20 times the dose of Fabrazyme for Fabry disease, a very, very large dose. And we supported in the end about 1,200 patients, which the equivalent of 25,000 Fabry patients, showed a production of Myozyme that primarily took place in Allston. How could we produce so much? We produced so much because in the beginning we were producing it for inventory, we were stabilizing it. But then eventually, we needed to keep producing it and take more reactor time, reactor time that really was dedicated to replenishing the inventories for Fabrazyme and Cerezyme. So since we had six to nine months of inventory for Fabrazyme and Cerezyme, we had quite a bit of time to absorb that inventory while we utilized the reactors to produce Myozyme. Then, of course, this virus hit. We put too much stress in the plant. ***We ran it 24 hours a day, over 100% capacity***. And then first, a warning signal, in terms of the warning letter from the FDA and then the virus hit at the most vulnerable moment.

202. Finally, Termeer acknowledged that the problems at Allston were due in part to the use of outdated equipment, and in part due to a culture of noncompliance that permeated the plant:

> So this consent decree question, is a great question, but it leads to a discussion of how did we get here, what caused this stress, what caused the warning, the out of compliance situation? And this one has an angle to it, in addition to plant, the ***Allston filling facility is compared to today's available technology old and we will not try to revive it other than just to bridge to the facilities in Boston***.
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> ***
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> [W]hen the plant gets into position like this, when you run it as hard as we ran it, you get a certain dynamic that takes very significant effort to work out of the plant. There is a human dynamic and we have people that are extremely familiar with that dynamic and that has managed these situations at Merck, or J&J, or at Wyeth, where they have occurred. And, so to get that dynamic, get beyond it, that's what the FDA wants to see… But there is clearly a problem here. There are 500 people in that plant and they operate in a way that it's - to the outsiders, it seems like you should ought to be able to do that just like that, but you can't. It is a dynamic to the plant that has to be worked very, very carefully and the culture

> in the plant, the discipline in the plant, all of that needs to be done and it need look peak performance of good behavior.

203. Termeer explained that the Company had replaced many of the managers associated with observations listed in the November 2009 483, and that many of the functions at Allston would be moved to other facilities around the world.

204. Further demonstrating the problems at Allston, on January 4, 2010, Genzyme issued a Form 8-K announcing that the Company would now outsource fill/finish manufacturing services for Cerezyme, Fabrazyme, Myozyme, and Thyrogen to Hospira Worldwide Inc., and that other fill/finish work would be transferred to existing contract manufacturers.

B. Genzyme's Competitors Gain Ground in Advancing Rival Drugs

205. As Genzyme continued to struggle with its manufacturing and compliance issues, its competitors gained ground. These competitors took steps to take advantage of problems at Genzyme even before the end of the Class Period.

206. Indeed, shortly after Genzyme announced the shut-down of the Allston plant in June 2009, the FDA reached out to rival manufacturers of competing Gaucher disease treatments in the development pipeline for help in dealing with the projected shortage of Cerezyme, and these competitors responded. For example, on July 6, 2009, at the FDA's request, Shire PLC ("Shire") filed a new treatment protocol for velaglucerase alfa ("Vela") as a substitute for Cerezyme. This protocol would allow doctors to treat patients with Vela on an early access basis, before the drug was commercially available. At the time, Shire was completing a Phase III clinical trial for Vela, and on July 16, 2009 Shire announced that the FDA had granted it fast-track status, which expedites review of new drugs in order to help get them into the market more quickly.

207. Similarly, on July 10, 2009, Protalix BioTherapeutics ("Protalix") announced that it, too, had been approached by the FDA, which had asked Protolix to consider submitting a treatment protocol for its Gaucher disease treatment, prGCD. At that time, Protalix was about to begin its Phase III clinical trials for prGCD.

208. On August 3, 2009, Shire announced (a) positive data from its Phase III clinical trials of Vela; (b) that it had begun its rolling submission of its NDA (New Drug Application) on July 30, 2009; and (c) that the FDA had accepted its proposed treatment protocol for Vela. Less than a month later on September 1, 2009, Shire also announced that it had completed the submission of its NDA for Vela and reported positive results on its final Phase III studies, which compared results obtained with Vela to those obtained with Cerezyme. Both studies showed that Vela had comparable safety and efficacy to Cerezyme.

209. Also in August 2009, Protalix received fast-track review from the FDA. Shortly thereafter, on September 14, 2009, Protalix announced completion of its pivotal phase III clinical trial for prCGD and projected that it would complete submission of its prCGD NDA by the end of the year. Protalix reported its top-line results from this trial in mid-October: in sum, prCGD, which will be marketed under the name Uplyso, achieved statistically significant improvement in baseline levels of key variables, and the drug was well-tolerated with no serious adverse events.

210. On November 4, 2009, Shire announced that the FDA had granted priority review for its Vela NDA. The priority review status accelerates the target review timing from ten to six months. For Vela, the FDA issued an action date of February 28, 2010. On February 26, 2010, Shire announced that the FDA granted approval for Vela to be marketed for the treatment of Gaucher disease.

211. Shire also capitalized on Genzyme's problems by moving forward to gain FDA approval for Replagal, a competing treatment for Fabry disease that had been commercially available outside the U.S. since 2001, which was likely to capture market share from Fabrazyme. On October 21, 2009, Shire announced its plans to file a BLA for Replagal by the end of the year. Shire also announced that its treatment protocol, filed at the request of the FDA, had been approved.

212. More recently, after the end of the Class Period, Shire announced on December 22, 2009 that it had actually filed its Replagal BLA, and emphasized its efforts to provide early access to the drug in light of the ongoing shortage of the existing treatment, *i.e.*, Fabrazyme.

213. Also in December, Protalix announced several key steps in its efforts to secure approval of prCGD. On December 1, 2009, Protalix entered into an agreement with Pfizer to develop and commercialize prCGD, and a week later Protalix announced completion of its NDA submission for the drug. Protalix also announced the filing of its proposed pediatric investigation plan with the Pediatric Committee of the EMEA with respect to a clinical study of patients between the ages of 2 and 18.

214. These advances by Genzyme's competitors were made possible by the contamination problems and resulting shortage of Genzyme drug products, and their continuing progress since the end of the Class Period has had a substantial adverse impact on Genzyme's business and financial prospects.

C. Ongoing Efforts to Unseat Defendant Termeer

215. Having suffered a collapse of the market price of Genzyme's stock, the investment community openly criticized Termeer and called for his ouster. Dubbing Termeer the worst biotech CEO of 2009, *TheStreet.Com*'s Adam Feuerstein observed, in an article published

on November 17, 2009, that Termeer "has driven Genzyme so far into the ground that a turnaround at the company will only come if Termeer resigns his CEO post," and said Termeer caused Genzyme's collapse because he "fostered an arrogant, irresponsible business culture in which employees are rewarded more for being loyal to the CEO than they are for being competent at their jobs. Genzyme doesn't address and solve problems, instead it merely whitewashes over them, hoping they either go away or can be disguised so well that no one notices." In fact, Genzyme's founder, Sheridan Snyder, who ran the company as CEO and chairman until Termeer took over, publicly stated that Termeer must resign his posts.

V. DEFENDANTS' FALSE AND MISLEADING STATEMENTS AND OMISSIONS DURING THE CLASS PERIOD

216. On October 24, 2007, the first day of the Class Period, Genzyme issued a press release, filed with the SEC on Form 8-K, announcing its results for the third quarter of 2007. Genzyme reported that its application for the approval of 2000L Myozyme – which would eventually be known as Lumizyme – would have an expected decision from the FDA in the first quarter of 2008. The release also stated that sales of Myozyme had increased to $53.6 million, from $20.4 million in the prior year period, and that sales of Fabrazyme and Cerezyme had increased 12% and 13%, respectively, from the prior year period.

217. Defendants Termeer, Meeker, and Wyzga participated in a conference call with analysts on the same day. Termeer told investors that "[t]his month we will file with the FDA the clinical data that they have requested for the approval of the large scale Myozyme manufacturing plant [the Allston plant] and ***we expect the approval to occur in the first quarter of next year***." Touting Myozyme's potential, Termeer noted that once Genzyme obtained approval for the 2000L reactor, it would get a "significant step function of revenues, in the U.S. and in overall Myozyme picture." According to Termeer the picture for Myozyme was "very,

very positive." Termeer stated that "a very, very strong picture is unfolding" and that Genzyme was "pretty bullish indeed" on the period from 2007 through 2011. Meeker also agreed that approval of Lumizyme was "expected to come in the first quarter of next year," allowing Genzyme to gain new commercial patients in the United States.

218. With respect to Cerezyme and Fabrazyme, defendant Wyzga told investors that "Cerezyme continues to make a solid contribution to our top line growth" due to increases in patient accruals, and that Fabrazyme increased by 12% due to new patient accruals.

219. Termeer also assured analysts that he saw little threat from competing LSD products, at least with respect to patients already being treated with Genzyme's drugs. As he put it, "we don't expect there to be, given the very long-term extremely solid experience that we have around Cerezyme to be any particular reason for patients to shift or to change…"

220. These statements were false and misleading for the following reasons:

A. The Company was not complying with CGMP at the Allston plant where its Genetic Diseases Segment drugs were manufactured. Specifically, as set forth in detail at ¶¶ 55-84, 99, 184 above, the plant suffered from very serious deficiencies, including the use of out-of-date equipment, poor training for employees, and lack of proper procedures to prevent contamination of the product.

B. Defendants failed to disclose that, as set forth in ¶¶ 83-84, 201 above, (a) Genzyme was only able to maintain growth rates for its LSD products by severely overburdening the Allston manufacturing plant, and (b) even as they touted the growing demand for Cerezyme and Fabrazyme, a significant portion of Allston's manufacturing capacity was being diverted

from those products and devoted to the manufacture of Myozyme, thereby severely depleting inventories of Cerezyme and Fabrazyme. As discussed at ¶¶ 83-84 above, particularly when coupled with Allston's woefully deficient compliance practices and resulting risk of contamination and/or regulatory action that would interrupt production at Alston, the Company's failure to maintain sufficient inventories created a particularly serious risk that Genzyme would be unable able to supply the market with Cerzyme and Fabrazyme and that it would suffer significant loss of revenue and earnings as a result.

C. Defendants failed to disclose that, as discussed above at ¶¶ 42-43, as a result of the stress placed on the Allston plant, coupled with the depth and pervasiveness of its woefully deficient compliance practices, Genzyme could not satisfy FDA requirements for the approval of Lumizyme.

D. As a result of the depth and pervasiveness of its woefully deficient compliance practices, contamination outbreaks and/or adulteration of its products, and/or serious adverse FDA action was likely if not inevitable.

E. Patients would have to switch to medications produced by Genzyme's competitors if Genzyme could not supply the market with its own products, and Termeer's claim that there was no reason to expect patients to switch from Cerezyme was untrue and lacked a reasonable basis at the time it was made, as discussed above at ¶¶ 86-87.

221. No Defendant who participated in the call corrected any of the misstatements of the other Defendants.

222. On January 8, 2008, Genzyme issued a press release, filed with the SEC on a Form 8-K, announcing results for its quarter ended December 31, 2007. Genzyme announced that quarterly revenues had increased from the prior year by 21% to $1.04 billion, and annual revenues had increased 20% to $3.8 billion. The press release specifically reported increases in sales of Genzyme's LSD segment drugs. Genzyme reported that Myozyme sales had more than doubled compared to the prior year period, and annual sales had more than tripled from the prior year. Genzyme reported that Fabrazyme sales had increased 18% from the prior year period, and 18% annually, capturing "more than two thirds of the international market for Fabry disease treatments, surpassing its competitor based on compelling clinical data and an established global regulatory and commercial organization." With regard to Cerezyme, Genzyme reported a 15% increase in sales from the prior year period, and an annual increase of 13%.

223. The press release quoted Termeer as stating that the Company had an "outlook for strong growth" and that the Company felt "bullish" as it looked "ahead at the picture that is unfolding for Genzyme." In the press release, Genzyme stated that "the growth potential" for the LSD products – which it characterized as "form[ing] the core" of its business – "remains strong," and claimed that sales of products from this segment would increase "at a compound average of approximately 13 percent over the five-year period from 2006-2011."

224. On February 13, 2008, Genzyme issued a press release filed with the SEC on a Form 8-K setting forth fourth quarter 2007 and full fiscal year 2007 results, and what it deemed its "outlook for continued strong growth in 2008 and beyond." The Company stated that "[s]ales of Myozyme are expected to increase to $320-$330 million this year, compared with $201 million last year. The launch of this product has been the most rapid for any of Genzyme's lysosomal storage disorder treatments."

225. On February 29, 2008, Genzyme filed with the SEC its Annual Report on Form 10-K for the fiscal year ended December 31, 2007, signed by defendants Termeer and Wyzga, and containing certifications signed by Termeer and Wyzga as required by the Sarbanes-Oxley Act of 2002, 15 U.S.C.A. §§ 7201 *et seq*. Genzyme reported revenues of approximately $3.8 billion and profits of approximately $480 million. With regard to Cerezyme, Genzyme reported total sales of $1.1 billion, which was 30% of total revenue in 2007. The Company attributed the 13% growth in sales of Cerezyme as compared the prior year "to our continued identification of new Gaucher disease patients." An 18% sales growth in Fabrazyme was attributed to "increased patient identification worldwide."

226. The 10-K also told investors that, "[a]ll facilities and manufacturing techniques used for the manufacture of Genzyme's products must comply with applicable FDA regulations governing the production of pharmaceutical products known as 'Good Manufacturing Practices,'" and described the Allston facility as "contain[ing] extensive sterile filling capacity."

227. The statements in ¶¶222-26 were false and misleading, omitted material information, and lacked a reasonable factual basis when made, for the reasons stated in ¶220, above. Additionally, Genzyme was not positioned for "strong growth" because it had overburdened the Allston plant beyond its capacity which, as Defendants knew or recklessly disregarded, presented a material (and undisclosed) risk of further deviations from CGMP and in turn (a) a severe risk of contaminations that would shut down production of Genzyme's key drugs and (b) FDA denial of the Lumizyme BLA.

228. On April 10, 2008, Genzyme filed a Schedule 14A with the SEC and disseminated a proxy statement to investors for Genzyme's annual shareholders' meeting. In the SEC filing, Genzyme noted that "key products" such as Cerezyme and Myozyme experienced

"continued strong growth," and that it had closed the year with "strong financial growth that exceeded the forecasted target and positioned the company well for 2008." The SEC filing stated that Termeer "continuously manages [Genzyme] toward sustainable future growth through . . . [s]trong commercial activity in domestic and current global markets" and "continued breadth and depth of the product pipeline." Genzyme also claimed that Termeer was "recognized for managing continuous growth and expansion of global manufacturing facilities, which provides multiple technology platforms across and within manufacturing facilities."

229. These statements were false and misleading when made, omitted material information, and lacked a reasonable factual basis when made, for the reasons stated at ¶220.

230. On April 21, 2008, Genzyme held a conference call with analysts in which defendants Termeer, Meeker, Wyzga, and Lawton participated. On the call, Genzyme told investors that it expected to receive approval for the 2000L product in late 2008, and to commercially market it in the United States in the first quarter of 2009. As Lawton stated, "we are now predicting the FDA action by the end of this year." Termeer likewise stated, "We now expect that commercialization of the 2000-liter material for late-onset patients in the United States will start in the first quarter of next year." He also noted that it would be inconvenient to have two different products – the 160L and the 2000L – on the market simultaneously, "So we would expect this to be a temporary position, but that's where probably we'll end up in the very beginning after the approval of the 2000-liter material late this year."

231. These statements were false and misleading, omitted material information, and lacked a reasonable basis when made, for the reasons stated in ¶220(A), (C).

232. No Defendant on the call corrected the false and misleading statements of other Defendants.

233. On April 23, 2008, Genzyme issued a press release, filed with the SEC on Form 8-K, reporting its results for the first quarter of 2008. The release announced "Total revenue for the quarter grew 25% to $1.1 billion from $883.2 million in [the] same period a year ago. This increase was driven by growth across all product lines, led by strong growth in sales of treatments for lysosomal storage disorders and renal disease." For the quarter, Genzyme reported that Myozyme sales rose 78% as a result of new patient enrollment and "robust" demand for the drug. Genzyme also reported a rise in Cerezyme sales of 15% over the prior year period, and a 16% increase in sales of Fabrazyme over the prior year period.

234. On May 9, 2008, Genzyme filed with the SEC its results for the quarter ended March 31, 2008 on a Form 10-Q signed by defendant Wyzga, and containing certifications signed by defendants Termeer and Wyzga as required by the Sarbanes-Oxley Act of 2002, 15 U.S.C.A. §§ 7201 *et seq*. For the quarter, Genzyme reported overall revenues of over $1.1 billion and profits of over $145 million. Product revenues of 15%, 16% and 78% for the quarter were reported for Cerezyme, Fabrazyme, and Myozyme, respectively. With regard to therapeutics, Genzyme reported an increase in revenues of 33% to $568.5 million for the three months ended March 31, 2008, as compared to the same period of 2007, due to continued growth in sales of Cerezyme, Fabrazyme and Myozyme. The Company attributed the growth in sales of Cerezyme and Fabrazyme to continued identification of new patients.

235. The Form 10-Q also stated that the BLA for 2000L Myozyme (Lumizyme), would be approved by the end of 2008. The 10-Q stated: "We anticipate that this process will culminate in the availability of two commercial versions of Myozyme in the United States: one produced at the 160L scale and the other produced at the 2000L scale…. We expect sales of

Myozyme to continue to grow and expect to begin providing U.S. patients with commercial 2000L Myozyme during the first quarter of 2009."

236. The statements in ¶¶233-35 were false and misleading, omitted material information, and lacked a reasonable factual basis when made, for the reasons stated in ¶220.

237. On July 23, 2008, Genzyme issued a press release on a Form 8-K filed with the SEC, announcing its results for the quarter ended June 30, 2008. The press release reported that second quarter revenue increased to $1.171 billion, as compared to $933.4 million in the prior year period, and quoted Termeer as stating that "[i]t was a strong and highly productive quarter. We delivered solid financial results, set in place a number of catalysts that will drive near-term growth, and continued to build the company to grow beyond 2011." Genzyme reported a 65% increase in Myozyme revenue over the prior year period, and "strong, double-digit growth" of sales of both Cerezyme and Fabrazyme. The press release repeated Defendants' earlier representations that Genzyme expected FDA approval of Lumizyme by the end of 2008.

238. That same day, Genzyme held an earnings conference call with analysts in which Termeer, Wyzga, and McDonough participated. Termeer described the second quarter as "very solid" financially and "an extremely productive quarter in terms of building for the future." Termeer once again boasted of Myozyme's rapid growth, calling it the "fastest growth rate that we've seen in any of our lysosomal storage diseases or any product for that matter." Wyzga also repeated the growth-in-sales figures of Cerezyme, Fabrazyme, and Myozyme from the press release. McDonough characterized Fabrazyme's growth in particular as "very strong" due to increased penetration of new geographic markets. McDonough also stated that until Genzyme was able to get a new 4000L plant in Belgium approved by European authorities, Myozyme

supplies would be "tight" and that Genzyme would "be very focused on managing in the best way."

239. In the conference call, Termeer reiterated his expectation that the Company would launch Lumizyme commercially in the United States in 2009. When one analyst directly asked whether the Company expected that the FDA examination of the Lumizyme BLA would focus more on manufacturing or on clinical data, Termeer responded: "Because the manufacturing side of it is what it is and the product is well characterized and the clinical data is really what the delay is all about. That makes us feel very good about that moment because we know what the clinical data told us."

240. On August 11, 2008, Genzyme filed with the SEC a Form 10-Q for the quarter ended June 30, 2008, signed by Wyzga and containing certifications signed by Termeer and Wyzga as required by the Sarbanes-Oxley Act of 2002, 15 U.S.C.A. §§ 7201 et seq. The Form 10-Q repeated the financial results and growth projections previously reported in the June 23, 2008 press release and conference call. The Form 10-Q attributed growth in Cerezyme and Fabrazyme sales to increased patient identification and increased expansion of Fabrazyme into new markets. Once again, Genzyme reported that the FDA would act on its Lumizyme BLA by the end of the year, "culminat[ing] in the availability of two commercial versions of Myozyme in the United States," *i.e.*, the existing 160L product and Lumizyme.

241. The statements in ¶¶237-40 were false and misleading, omitted material information, and lacked a reasonable factual basis when made for the reasons stated in ¶220.

242. In addition, McDonough's claim that while Myozyme supplies were "tight" the Company would "be very focused on managing in the best way" was false and misleading because Genzyme continued to depart in significant ways from CGMP and did not manufacture

sufficient quantities of its most important products to respond to the virtually unavoidable consequences of its violations of CGMP: two contaminations at the Allston plant and a shutdown of its manufacturing processes.

243. Additionally, Termeer's claim that the FDA would only focus on the clinical data was false because, as Termeer knew or was reckless in not knowing, FDA regulations required that Allston be in compliance with CGMP before any drug manufactured at that facility could be approved for commercial sale, and the Allston plant violated CGMP in numerous respects.

244. No Defendant participating in the conference call corrected the misleading statements of the other Defendants.

245. In September 2008, Genzyme experienced the Vesivirus 2117 contamination at its Geel plant. Defendants never disclosed the contamination until June 16, 2009.

246. On September 23, 2008, Genzyme issued a press release titled "Genzyme Provides Details of October Myozyme Advisory Panel Meeting and Additional Regulatory Updates." In the press release, Genzyme reported that it expected the FDA to approve its Lumizyme BLA by the PDUFA date of November 29, 2008. Lawton was quoted as stating that Genzyme was "confident that the strong clinical data from the LOTS [Late Onset Treatment Study] trial will support U.S. approval of [Lumizyme]. We are working cooperatively with the FDA to move this process forward expeditiously so that we can provide broader access to treatment as soon as possible."

247. This press release was false and misleading for the reasons stated at ¶220(A) and (C), above.

248. On October 10, 2008, the FDA issued the October 2008 483 to Genzyme setting forth the numerous major deficiencies in manufacturing practices at the Allston plant.

249. On October 22, 2008, Genzyme issued a press release on a Form 8-K filed with the SEC, announcing financial results for the quarter ended September 30, 2008. Defendants stated that revenues had increased 21% in the third quarter, driven by "double-digit growth in every Genzyme business unit." Genzyme reported that sales of Myozyme, Cerezyme, and Fabrazyme increased, with sales of Fabrazyme specifically attributed to growth in new patients. Termeer claimed that "the third quarter was a very strong quarter financially and also extremely productive in terms of building for the future." The release stated that for 2009, Genzyme expected non-GAAP earnings to increase to approximately $4.70 per diluted share.

250. Despite having received the October 2008 483 just twelve days earlier, Genzyme omitted from the press release any mention of the Form 483, the serious deficiencies in manufacturing practices found by the FDA at the Allston plant, or the contamination in Geel, Belgium. Nor did the press release retreat from Genzyme's earlier representations that it expected the Lumizyme BLA to be approved by the end of the year. Instead, the press release falsely reassured investors that Lumizyme was still on track for November approval, stating: "FDA action on the BLA for Myozyme (alglucosidase alfa) produced at the 2000L bioreactor scale is expected by November 29, 2008. An FDA advisory committee yesterday affirmed that the Late Onset Treatment Study established the clinical effectiveness of alglucosidase alfa produced at this scale."

251. On October 22, 2008, Genzyme also held an earnings conference call with analysts, in which defendants Termeer, Wyzga, McDonough, Lawton, and Meeker participated. Defendants still made no mention of the Geel contamination or the serious deficiencies at the Allston plant that called into question the Company's ability to obtain timely FDA approval of Lumizyme. Instead, Termeer described the quarter as "very robust," and declared "double-digit

growth throughout all of our businesses." Defendants continued to tout growth in sales and demand for Myozyme, Cerezyme, and Fabrazyme. Wyzga told investors that revenue "increases were driven by the strong ramp rate that we are still seeing in Myozyme, as well as strong Fabrazyme … revenue increases," and McDonough stated that, with respect to Cerezyme, "[g]lobal patient identification rate has held steady in 2008 and also year-on-year, and we continue to make progress, both in mature and in developing markets." McDonough repeated the sales increases in Myozyme, Fabrazyme and Cerezyme that had been reported in the October 22, 2008 press release.

252. Rather than disclose the October 2008 483, Defendants continued to present the same positive assessment of the likelihood of obtaining FDA approval of the Lumizyme BLA that they had been presenting over prior months. Specifically, Termeer stated in the conference call:

> I am very happy indeed that, yes, that there was an Advisory Committee meeting to discuss our BLA for the 2000-liter, and that was a positive meeting, as all of you have picked up by now, I am sure. There is a PDUFA date later in November, I believe November 29, and we will be working very hard with the FDA to get everything done at that time, that still needs be done, but it was very, very gratifying indeed, to see that in this meeting, the real need for this product to be released in the United States was being recognized. We see great, great potential for this product.

253. When asked by an analyst about potential FDA requirements for post-marketing studies before approving Lumizyme, Termeer reiterated that "we work very hard to meet the requirements to get it all done by the PDUFA date [November 29]."

254. Termeer also confirmed the projection of $4.70 earnings per share for fiscal year 2009 contained in the press release. That figure assumed FDA approval of Lumizyme for commercial sale in the U.S. in 2008. Termeer told investors that the Company was "in a very robust position" to meet that projection.

255. In the October 22, 2008 conference call, McDonough similarly made no mention of the October 2008 483 when he stated that the FDA Advisory panel had accepted the clinical data on Lumizyme with no age restrictions for patients. McDonough also reiterated that Genzyme expected the FDA to take action by November 29, 2008. McDonough even told investors that "the likelihood of approval seems to be more certain, or at least is taking a more solid shape" than in the previous quarter. When questioned by an analyst, McDonough told investors that the projected earnings per share of $4.70 assumed that the Company experienced no capacity constraints on Myozyme in the second half of 2009. Even when one analyst directly asked whether anything was "discussed during the closed manufacturing session that may affect the approvability of Myozyme," none of the Defendants made any mention of the fact that the FDA had just issued a Form 483 identifying severe manufacturing deficiencies at Allston. Instead, Lawton merely stated: "It was really just a discussion about the biochemical differences that we know exist between the 160 and the 2000-liter scale," and that the clinical data was the "most important piece."

256. In November 2008, the Allston plant experienced the same contamination that had plagued the Geel plant.

257. On November 7, 2008, Genzyme filed with the SEC its Form 10-Q for the quarter ended September 30, 2008, signed by Wyzga and containing certifications signed by Termeer and Wyzga as required by the Sarbanes-Oxley Act of 2002, 15 U.S.C.A. §§ 7201 et seq. For the quarter, Genzyme reported overall revenues of over $1.1 billion and profits of over $119 million. The 10-Q repeated the financial information from the October 22, 2008 press release and conference call, and attributed growth in Cerezyme and Fabrazyme sales to identification of new patients.

258. As with the October 22, 2008 press release and conference call, the November 7, 2008 Form 10-Q made no mention of the October 2008 483 or of the two contamination outbreaks, and continued to assert that Genzyme expected the FDA to approve its Lumizyme application in November 2008 with no indication that there had been any material changes in the status of the application. Specifically, just as in earlier filings, the 10-Q stated: "We expect the FDA to act on the BLA by November 29, 2008" which would "culminate in the availability" of Lumizyme, with commercial sales beginning in the first quarter of 2009. The 10-Q stated that "[w]e expect demand for Myozyme to continue to grow and expect to begin providing U.S. patients with commercial 2000L product during the first quarter of 2009." The 10-Q also stated: "To meet the global demand for Myozyme, we are working to secure approval from the EMEA to produce Myozyme at our 4000L scale manufacturing facility in Belgium. . . . Product supply of Myozyme is expected to remain tight until the 4000L process is approved."

259. The statements in ¶¶249-55, 256-58 were false and misleading, omitted material information, and lacked a reasonable basis when made for the reasons stated in ¶220, above. Additionally, the statements were false and misleading because:

A. Defendants continued to represent that Lumizyme would soon be approved without any indication that there had been any changes to the status of the application. In fact, however, the October 2008 483 – issued pursuant to the necessary pre-approval inspection of the Allston facility – made it clear that the FDA was aware of the deficiencies and did not believe that the plant complied with CGMP, a necessary precondition for Lumizyme's approval under applicable FDA regulations. By failing to disclose the October 2008 483, Defendants misled investors into believing

that no impediments to approval had arisen. Indeed, Defendants continued to tell investors that Lumizyme would be approved even though their own plan to rectify the deficiencies identified by the FDA would not be completed until March 31, 2009, ¶ 100, after the PDUFA date, and Defendants failed even to implement their promises to the FDA, as described above at ¶¶ 65-66, 71, 74, 101-02, 162, 170-71, 185, 192-94.

B. Defendants failed to disclose the October 2008 483, the numerous CGMP violations discussed therein with regard to the Allston plant, or the materially heightened risk that those violations would lead to contamination or adulterated products at Allston, as had recently occurred (but not been disclosed) at Geel.

C. Defendants failed to disclose that "tight" inventories of Myozyme were exacerbated by contamination, as described above at ¶104.

D. The condition of the Allston plant, the two contaminations, and the October 2008 483 jeopardized the Company's ability to produce sufficient product to meet its projections, at described above at ¶¶42-43, 83-84, 104-105.

260. No Defendant corrected the misleading statements of other Defendants on the conference call.

261. On November 17, 2008, the Company issued a press release announcing that the FDA viewed certain of the Company's submissions as major amendments to the Lumizyme BLA. The FDA had therefore extended the PDUFA date by 90 days to February 28, 2009. The release stated that Genzyme did not expect the extension to have any effect on its 2009 non-

GAAP earnings per share, and reconfirmed its non-GAAP earnings guidance of $4.70 per share for 2009.

262. Defendants' statements in this press release were false and misleading, omitted material information, and lacked a reasonable basis for the reasons stated at ¶¶220(A) and (C), ¶259 (A-B) and (D).

263. On January 13, 2009, Defendants issued a press release, filed with the SEC on a Form 8-K, reporting earnings results for the quarter ended December 31, 2008. The press release described the Genetic Disease Segment as having "formed the core of Genzyme's business to date," and stated that the "growth potential for this segment remains strong." The release stated that the segment grew 26% in 2008 to $2.2 billion from $1.8 billion in 2007, and reported that Myozyme fourth-quarter revenue increased 20% to $75 million from the prior year period, and that fourth-quarter sales of Fabrazyme increased 10%.

264. The press release also stated that in 2009, the Company "expects to… [o]btain regulatory approvals for larger-scale production of Myozyme," *i.e.*, Lumizyme. The release warned that "[f]rom January through April of this year, inventory levels [of Myozyme] are expected to be so tight that there is a risk of delays in order fulfillment and consequent potential interruptions in therapy." The Company projected earnings $4.70 per share and revenues between $5.2 and $5.4 billion in 2009.

265. These statements were false and misleading, omitted material information, and lacked a reasonable factual basis when made for the reasons stated above at ¶259.

266. In a press release issued on February 11, 2009 and filed with the SEC on a Form 8-K, Genzyme announced its fourth-quarter 2008 and fiscal year 2008 results and provided projections for 2009. Termeer noted that the Company "had an excellent year last year and

exceeded [its] earnings expectations despite the economic environment and the challenges [it] faced with Myozyme." For Myozyme, the Company projected that revenue would increase to $430-$440 million, up from $296 million in 2008. Genzyme also stated that it anticipated that:

> its non-GAAP earnings will accelerate starting in the second quarter, as two key regulatory approvals for Myozyme are secured: E.U. approval of Myozyme produced at the 4000 L scale, which will help provide the capacity to meet the strong global demand for the product; and U.S. approval of Myozyme produced at the 2000 L scale, which will be called Lumizyme, giving the company the ability to promote the Pompe disease therapy produced at this scale in the U.S. market.

The release stated that approval of Lumizyme was expected by the PDUFA date of February 28, 2009. Genzyme also projected that revenue from Fabrazyme would increase from $494 million in 2008 to $560-$570 million in 2009, and that revenue from Cerezyme would increase from $1.24 billion in 2008 to $1.25-$1.28 billion in 2009. The press release also mentioned that due to "incomplete process validation runs" at the Belgium plant, the Company would write off $33 million in expenses and inventory.

267. On February 11, 2009 Genzyme held an earnings conference call with analysts in which Termeer, Wyzga, McDonough, and Lawton participated. Termeer began the call by describing the fourth quarter ended December 31, 2008 as "very robust," with revenues up 13% for the quarter and 21% on a year-to-year basis. Termeer noted that Genzyme's diversification "in terms of geographies where we operate" was a strength, and added: "Same thing for our manufacturing. We pretty much produced half our products in Europe and the other half in the United States.... [T]his global diversification, with products and operations is clearly very beneficial in managing through these very tumultuous times and it is on that basis that we feel again very confident to talk about our guidance for the coming year."

268. In the conference call, McDonough reported revenues from Fabrazyme of $494 million, a 16.5% year-on-year increase attributed to "strong patient accruals globally."

According to Wyzga, Fabrazyme sales were expected to increase by nearly 14% compared to 2008, to between $560 million and $570 million for 2009. With regard to Cerezyme, McDonough reported 2008 revenues of $1.24 billion, a 9.3% year-on-year increase. McDonough noted that "worldwide patient accruals" for Cerezyme had been "strong" in 2008. According to Wyzga, revenues from Cerezyme, described as a "key business driver" were expected to "come in between $1.25 and $1.28 billion" for 2009. McDonough also anticipated "robust growth for Cerezyme on a volume basis" in 2009.

269. Without mentioning either the October 2008 483 or the fact that Genzyme's own plan to address the numerous CGMP deficiencies did not envision resolution before March 31, 2009, Termeer stated that he expected Lumizyme to be approved by the FDA on its PDUFA date of February 28, 2009: "[I]n the U.S. it [Lumizyme] was a product that we couldn't promote and actually we were giving and are giving product free of charge to many patients in the United States. We expect that to be resolved during this quarter. We have a PDUFA date by the 28th of February. We will again get the 2000 L profusion reactor system approved."

270. Wyzga similarly stated that the Company "expected" Lumizyme approval, and that as a result, Genzyme expected that Myozyme revenue would "increase … by almost 50% on a year-to-year basis." McDonough added that the approval process for Lumizyme "continue[s] to be on track" for approval on February 28, 2009. McDonough also noted that the Company was "operating in a situation today with very tight inventories" of Myozyme, but that was expected to change once the Company obtained FDA approval of Lumizyme and European approval of the 4000L plant in Belgium.

271. During the call, an analyst asked about the reason for the incomplete validation runs in Belgium. McDonough answered: "I think the process validation for any new facility

does involve runs that are either stopped or abbreviated for a variety of reasons. These PV runs that Mike referred to were not part – or not considered to be part of the formal run up to the submission. So the way to think about that is part of the normal development process that we would undergo for a new facility."

272. The statements in ¶¶ 266-71 were false and misleading, omitted material information, and lacked a reasonable factual basis when made for the reasons stated at ¶259, and because:

A. Defendants were not in a position to meet the demand they described for Cerezyme and Fabrazyme. The Allston plant was operating beyond its capacity, and Defendants had not manufactured sufficient quantities of Cerezyme and Fabrazyme to meet demand. Indeed, by now Defendants were also aware that they had twice experienced contaminations that slowed down production – once in Geel, and once in Allston – making their depleted inventories of Cerezyme and Fabrazyme, as well as their continuing noncompliance with CGMP at Allston, virtually certain to prevent Genzyme from meeting its projected revenues, income and earnings. Nonetheless, Defendants continued to create the false impression that Genzyme could meet increased demand for Cerezyme and Fabrazyme, and failed to disclose the known constraints on Genzyme's ability to meet that demand or the contamination that had, by then, twice interrupted production.

B. Defendants failed to explain that the tight supply of Myozyme was a direct result of contamination. Defendants' statements regarding "incomplete

> process validation runs" were misleading because Defendants failed to mention that these failed runs were a result of the contamination, and were not part of ordinary start-up costs for a new plant. As McDonough would later admit on June 24, 2009, Genzyme launched a six-month investigation into the problems at Geel when they arose. "We did have indications that a virus could be one," he told analysts in June, "but it was one of several dozen possibilities on a long list of things that can contribute to a cell-culture decline. As a result, last year we fully cleansed, using the same procedure, the Geel facility…."

273. No Defendant corrected the misleading statements of other Defendants on the conference call.

274. On February 27, 2009, the Company received the February 2009 Warning Letter and the Complete Response Letter from the FDA. In response, Defendants decided not to market Lumizyme commercially.

275. After the close of trading on Monday, March 2, 2009 Genzyme issued a press release announcing a conference call to be held at 5:00 p.m. that day. The press release stated that the Company had received the February 2009 Warning Letter and the Complete Response Letter. Termeer was quoted as stating that "We are confident we will be able to resolve all remaining issues with the FDA within three to six months." The release also stated that Genzyme believed it had "readily at hand" all the information requested by the agency, and that it would be able to submit this information within approximately one month. Genzyme stated that it was "confident that the products produced at the Allston facility continue to meet the highest quality and safety standards." In the event of a six-month delay in Lumizyme's

approval, Genzyme anticipated the impact on 2009 non-GAAP earnings to be approximately $0.12 per share. With such a delay, Genzyme stated that it expected Myozyme revenue of $370 – $380 million in 2009.

276. Defendants failed to reveal in either the press release or in the analyst conference call the prior two contaminations that had slowed production in Geel and Allston. Instead, on the call, in which defendants Termeer, Lawton, McDonough, Bamforth, and Wyzga participated, Termeer told analysts:

> For purposes of calculating the impact of this delay, we've indicated in the press release that if there's a six month delay, that will have an impact of $0.12, non-GAAP earnings per share; if it is less delayed, than it will have a proportionate[ly] less impact. The main thing is that on one hand we have this delay; on the other hand we have a very high level of confidence indeed that we will get through this approval and that we will be able to start to make product available to all patients.

277. In direct response to an analyst's request during the call for clarification on the timeframe, Termeer reiterated: "We also feel, and I witnessed it myself; that the FDA is on the ball here, is with us. We feel good response from everybody. But everybody in our industry is currently having these experiences, particularly on items like REMS and stuff like that. So we thought it would be wise to talk about it in three or six months. Obviously if we get it faster, that's good news."

278. Lawton similarly told investors:

> I can say that after we received the 483 in October, we actually submitted responses to the FDA at the end of October with a complete plan of how we intended to respond to each one of the items in the 483. And that action plan, we have actually been carrying out and we are on track with everything that we committed to the FDA. In fact, last week [February 23] we sent an update to the FDA, informing them of the progress that we had made to that plan and showing them that we were indeed delivering on the action items that we had committed to. Now the warning letter itself raises just a couple of additional questions. But these are really just elaborations on that original 483. And we are actually confident at this point that we're going to be able to respond in full to the warning letter by the end of this week.

279. In response to an analyst's question about how Genzyme could be so certain that it could quickly satisfy the FDA's concerns, Lawton stated that: "the update that we sent to the FDA last week on the activities that we had conducted and committed to back in October, that was a very high-level update to the FDA. I think that in order to resolve the warning letter, they will want to see the details behind that. That's been our experience in the past and we're very confident that we have all of that documentation to give to them."

280. Defendants continued to speak as though Genzyme intended to market Lumizyme commercially. Lawton stated, "Obviously … we have a complex situation with Myozyme [160L] being approved in the US with the broad label and the fact that it will overlap with some of the indications on the Lumizyme [*i.e.*, the 2000L product produced exclusively at Allston], *even though we're keeping Lumizyme for the adult population*." McDonough said, "So I think the comments here today reflect our commitment to bring this near-final phase of the 2000 liter approval to its natural conclusion here in the US to broaden access and fully satisfy the demand for Lumizyme, in this case for US Pompe patients… We continue to feel that Myozyme and Lumizyme will meet their full potential to serve the Pompe community with a corresponding commercial picture similar to that of Cerezyme as we enter this final phase of approvals."

281. After an analyst asked whether a new inspection would be required before the FDA could determine whether the issues identified in the February 2009 Warning Letter were resolved, Bamforth said, "We don't expect that. Clearly, the FDA has the liberty if they choose to do a follow up to require that. But that's not an automatic requirement. And you'll recall that we had an issue with our Lyon facility and they didn't require an inspection to lift that warning letter."

282. In response to a direct question by an analyst, Bamforth stated, "[T]hese observations at Allston apply to all the products manufactured at Allston and – but we don't anticipate that these observations will have any impact on our supply.... [We] have been working through them and dealing with the more critical ones as quickly as we could. So we don't anticipate that having any issue with supply."

283. At 4:48 p.m. on March 2, 2009, Defendants filed with the SEC their 2008 10-K, signed by Termeer and Wyzga, and containing certifications signed by Termeer and Wyzga as required by the Sarbanes-Oxley Act of 2002, 15 U.S.C.A. §§ 7201 *et seq*. Genzyme reported revenues of over $3.8 billion and profits of over $480 million. As with the March 2, 2009 press release and the conference call, the Form 10-K made no mention of Defendants' new plan to stop manufacturing Lumizyme at Allston and instead to merely use the Lumizyme BLA as a basis for seeking approval of the 4000L product. Instead, the Form 10-K represented: "If this application is approved by the FDA, the product produced using the 2000L scale process will be marketed as Lumizyme in the United States."

284. The Form 10-K went on to tout the "growth" in Genzyme's LSD segment drugs, reporting that Cerezyme sales constituted 27% of total revenue in 2008, a 9% increase over the prior year, attributed to continued identification of new Gaucher disease patients. With regard to Fabrazyme, Genzyme reported total sales of $494.3 million, which constituted 11% of total revenue in 2008, and a 16% increase as compared the prior year. This increase was also attributed to increased patient identification worldwide as Fabrazyme was introduced into new markets.

285. In its discussion of Good Manufacturing Practices, the Form 10-K mentioned the February 2009 Warning Letter, but additionally stated that notwithstanding the deficiencies it

identified, "[w]e believe that the products produced at our Allston facility continue to meet the highest quality and safety standards." The 10-K also described the Allston facility as "contain[ing] extensive sterile filling capacity."

286. Finally, the 2008 10-K also reported that "[i]n December 2008, we wrote off Myozyme inventory costs of $12.6 million related to terminated production runs during 2008 at our Belgium facility. Subsequent to December 31, 2008, additional terminated production runs at our Belgium facility were identified. Therefore, we anticipate writing off additional Myozyme inventory valued at approximately $9 million in the first quarter of 2009." As with the March 2, 2009 conference call and press release, the Form 10-K made no mention of the two contaminations that had occurred in Allston and Geel, nor of the fact that Allston continued to operate in a state of non-compliance with CGMP.

287. The statements in ¶¶ 275-86 were false and misleading, omitted material information, and lacked a reasonable factual basis when made for the reasons stated in ¶ ¶ 220(A-C), 259(D), 272(A), and because:

A. Defendants knew or were reckless in not knowing that the problems in Allston were ongoing and would not be resolved by the corrective measures they had proposed to the FDA, and certainly would not be resolved in the short time frame that Defendants described. As the FDA later concluded, and as Defendants were aware, Allston's deviations from CGMP were severe, and included a basic failure to conduct follow-up investigations into defective products, use of outdated equipment, failure to take measures to prevent contamination, and failure to properly train employees. ¶¶ 55-84, 99, 101-02, 162, 170-71, 184-85, 192-93.

Moreover, as the FDA would later conclude, Genzyme had failed even to implement its own plans for resolving these issues that it had submitted to the FDA in response to the October 2008 483 and the February 2009 Warning Letter, as described at ¶¶ 65-66, 71, 74, 101-02, 162, 185. Indeed, Defendants were well aware of the severity of the problems because the February 2009 Warning Letter prompted them to abandon their plan to manufacture Lumizyme commercially at Allston, as described in ¶ 199.

B. Although Defendants had determined that Allston could not handle the necessary manufacturing and that therefore they would only market the 4000L product from Belgium (which was not known as Lumizyme), Defendants continued to claim that Genzyme intended to market Lumizyme commercially in the United States after the BLA was approved, as described in ¶ 199.

C. The products produced at Allston did not meet the "highest quality and safety standards" for the reasons stated at ¶¶ 55-84, 99, 184, 192-94. In fact, the Allston plant had already experienced at least one contamination and the FDA would find that products produced at Allston were contaminated with bits of metal and other debris, attributable both to Defendants' departures from CGMP and to the use of aging, improperly maintained equipment.

D. The FDA would and did require a re-inspection. In fact, though McDonough told investors that after receiving a warning letter in Lyon no

re-inspection had been required, the Lyon facility had, in fact, been re-inspected, as described in ¶ 132.

288. No Defendant corrected the misleading statements of other Defendants on the conference call.

289. On March 11, 2009, the *Wall Street Journal* reported that Bamforth "said the company has addressed 80% of the problems cited by the FDA and expects to resolve all of the issues by the end of April…. He said the Boston plant continues to produce treatments and that 'the efficacy and safety of our products is unchanged.'" Bamforth's statements were false and misleading and lacked a reasonable factual basis when made for the reasons identified above at ¶¶ 55-84, 99, 101-02, 162, 170-71, 184-85, 192-93.

290. On March 24, 2009, Genzyme issued its 2008 Annual Report to shareholders. The report stated: "We anticipate U.S. approval of our Pompe therapy manufactured at the 2,000-Liter bioreactor scale, which we will call Lumizyme, in mid-2000." The Company stated that after this and approval of the 4000L plant in Geel, "production capacity for our Pompe therapy will allow us to treat patients around the world and support peak revenues of over $1 billion."

291. On April 22, 2009, Genzyme issued a press release, filed with the SEC on Form 8-K, titled "Genzyme Reports Solid Financial Results for the First Quarter of 2009." Genzyme attributed flat Myozyme sales to supply constraints. Once again, Defendants did not disclose that these supply constraints were attributable to contamination problems that had occurred during the fall of 2008, which had still not been disclosed. The Company also reported growth in Fabrazyme revenues, an increase in patients initiating Cerezyme therapy, and reaffirmed its revenue and earnings guidance for 2009. In the press release, the Company reported that it had

written off over $9 million "of inventory associated with incomplete production runs at our Belgium facility."

292. That same day, Genzyme held an earnings conference call with analysts in which Termeer, Lawton, Wyzga, and McDonough participated. Defendants repeated the financial information contained in the press release, and Termeer stated, "we are managing the company in a very conservative way as a result, not taking for granted that everything will happen the way that we wish it to happen. But we are very secure indeed, sufficiently secure in our conviction with regards to the business and the results that we can reach for us to reiterate the forecasts that we -- the guidance that we gave in February."

293. McDonough highlighted the continuing "growth" that the Company had been experiencing in its Genetic Diseases Segment: "We continue to see strong demand across the genetic disease portfolio with increasing volumes year-on-year on all products with the obvious limitations for Myozyme as mentioned… [T]he underlying accrual numbers on a per patient basis for each of the products [in enzyme replacement] remains strong and does not reveal for me a concern of the overall health of the business…. We're seeing on a global basis year on year the number of patients on each of the products increasing. And just to give you a flavor, given the size of our business and size of some centralized purchasers, we can see swings quarter to quarter in excess of $10 million unrelated to inventory or patient numbers, just related to purchasing patterns." McDonough also reported "steady growth year on year posting 5.5% on a volume basis" for Cerezyme, and a 16% year on year volume growth for Fabrazyme driven by new patient accruals.

294. Lawton revealed that, contrary to statements made on the prior call, the FDA would re-inspect Allston. Nonetheless, Lawton continued to offer a falsely positive view of the

status of the Lumizyme application, telling investors that Genzyme had essentially responded to all of the issues identified in the February 2009 Warning Letter, and to expect approval in the second or third quarter of 2009:

> We are on schedule with all of corrective actions in response to this warning letter, and specifically all of the corrective actions for Allston have been completed with the exception of one additional fill study which is unrelated to Lumizyme… We have actually been providing FDA weekly updates with information and data as we collect it. And are currently awaiting right now for their reinspection in order to resolve our compliance status. So we are very confident at this point that we've fully addressed all of the items in the warning letter and we actually look forward and welcome the FDA and reinspection…. So at this point we've actually resolved all of any outstanding items with FDA. And we are ready to submit our full package which will address all of the items in the FDA complete response letter. And we're really just waiting now for the reinspection of the Allston facility and the resolution of our compliance status before we can officially submit that document to the FDA. We believe we're still on schedule for that submission in this quarter, and with approval in late Q2 and or sometime in Q3.

295. When asked why she believed that the Company would obtain such quick approval, Lawton responded:

> Let's assume a worst-case, and that [our application] is classified as a class two, which is a six-month PDUFA date, the FDA have made it very clear with us that part of the reason that they wanted to continue to work with us now around finalizing the label and the REMS and the verification study, so that when we actually submit our package in response to the CR letter, the FDA will know what we're submitting. We've already agreed on the different parts on the FDA have basically told us that they would be working to expedite that review knowing that go they are fully informed and aware of what we're submitting back to them. So that's why we don't expect to take that full six months.

296. The Company also continued to refer to its "tight" Myozyme inventories without explaining that the shortage was exacerbated by the as-yet-undisclosed viral outbreak in late 2008. McDonough stated: "As expected Myozyme was constrained this quarter due to tight inventories as we transitioned to 4,000 liter supply in Europe which was approved there in February. Revenue was down slightly quarter on quarter and flat year on year as a result of voluntary missed doses by adults worldwide to protect access for infants and children…"

297. On May 6, 2009, the Company issued a press release announcing an analyst day meeting. The press release "outlined [the Company's] plans for continued sustainable growth across each of its businesses" and offered revenue guidance for 2009 of "$5.15 – $5.35 billion and revised its non-GAAP EPS from $4.58 to $3.52." With respect to the Lumizyme BLA, Genzyme stated that "Genzyme anticipates this to be a class 2 resubmission with a six-month PDUFA goal. However, given the ongoing dialogue between Genzyme and the FDA, the company expects that the agency will expedite the review process." At the analyst meeting on the same day, which was attended by Termeer, Wyzga, Lawton, and McDonough, Lawton repeated that the Company expected the new submission to have a six-month PDUFA date, and added "[b]ut I think what you have seen and what we are very confident in is we've been working really closely with the FDA, and they have clearly been working with us. They've said all along that they're going to work to expedite this approval, so I think we are confident that they are not going to take that full six months, and that approval will be earlier than that."

298. On May 8, 2009, Genzyme filed with the SEC its Form 10-Q for the quarterly period ended March 31, 2009, signed by defendant Wyzga, and containing certifications signed by defendants Termeer and Wyzga as required by the Sarbanes-Oxley Act of 2002, 15 U.S.C.A. §§ 7201 *et seq*. The Form 10-Q repeated the financial information from the press release and conference call. For the quarter, Genzyme reported overall revenues of over $1 billion and profits of over $195 million. Once again, flat sales of Myozyme were attributed to "the product not yet being approved for promotion in the U.S. market and by a global supply management program under which adult Pompe disease patients temporarily adjusted their infusion schedules in order to preserve constrained product supply for infants and children." Though the Company reported a "$9.2 million write off of Myozyme inventory costs related to incomplete production

runs during the first quarter of 2009 at our Belgium facility," no mention was made of the contamination that had slowed down production in Geel and Allston, and that was the cause of the incomplete production runs.

299. With respect to the February 2009 Warning Letter, the 10-Q stated: "We submitted an initial response to the FDA on March 6, 2009 with a plan and timeline for providing this supplemental information and have been providing regular updates to the FDA on our progress against this plan. We believe that we have addressed all the measures required to respond to the FDA warning letter." As on the conference call and in the May 6 press release, the Company again told investors that although it was expecting a six-month PDUFA date, it believed that the FDA would approve Lumizyme before that time: "Because our submission will include clinical data, we believe that the FDA will classify our response as a Class 2 resubmission with a six-month review period under the Prescription Drug User Fee Act, or PDUFA. However, given our ongoing dialogue with the FDA, we believe that we could receive approval before the PDUFA date."

300. The statements in ¶¶ 290-99 were false and misleading, omitted material information, and lacked a reasonable factual basis when made for the reasons stated at ¶ 220 (B-C), 259(C-D), 287, and because, as Meeker would admit at the end of the Class Period, ¶¶192-93, Defendants knew that they had not addressed all of the issues identified in the February 2009 Warning Letter. Among other things, when the FDA later issued a second Form 483 on November 13, 2009 – a Form 483 that Defendants themselves insisted merely elaborated on the same issues that had been identified in the October 2008 483 and the February 2009 Warning Letter – Meeker would tell investors that the issues highlighted by the FDA were ones "which we were very aware of and were working to address" and were "things that we understood and

were working towards." Additionally, as the FDA would point out in its July 27, 2009 letter, and as Defendants would admit in their August 14, 2009 response, there still remained serious unresolved compliance issues at Allston.

301. No Defendant corrected the misleading statements of the other Defendants on the conference call or at the analyst meeting.

302. On May 21, 2009, Genzyme issued a press release titled "Genzyme Submits All Information Requested by FDA for Lumizyme," stating that it had submitted the final documentation needed to address all the items in the FDA's Complete Response Letter. Once again, the Company stated that it anticipated that the filing would be designated as a class 2 resubmission with a six-month PDUFA goal but that "given the ongoing dialogue between Genzyme and the FDA, the company expects that the agency will expedite the review process." With regard to the February 2009 Warning Letter, Genzyme reported that it had completed all of the measures required regarding its Allston facility.

303. Genzyme's statements regarding its purported completion of measures required to respond to the February 2009 Warning Letter were false and misleading for the reasons stated at ¶¶ ¶¶ 65-66, 71, 74, 101-02, 162, 170-71, 185, 192-94.

304. On June 16, 2009, Genzyme announced the viral outbreak at Allston and the shutdown of the plant for sanitization procedures. In a conference call that day, in which Termeer, Meeker, Lawton, McDonough, Bamforth, and Wyzga participated, Defendants insisted that although they had not identified the source of the contamination, the contamination had nothing to do with the general compliance issues identified by the FDA. This was because, Defendants claimed, the FDA had previously signed off on the plant during the May inspection and had agreed that the compliance issues had been resolved. Lawton stated:

> [T]his particular event is very distinct and separate from the compliance issues at Allston. And I wanted to just note that I think we had informed people in a press release that the inspection, the reinspection of the Allston facility had started in May. And I did want to let everyone know that that inspection actually closed out with the inspector informing us that we had indeed satisfactorily addressed all of the items in the warning letter for Allston. So from that respect, that does not impact in any way the Lumizyme approval and is no longer a gating issue on that item.

305. Termeer admitted that the Company had not received a formal communication from the FDA signing off on Allston, but Lawton insisted that such a formal communication was not important: "I think, actually, rather than the written communication, to us what's most important is the communication from the inspector and the district office that conducted that inspection to the compliance group at FDA, who then inform the reviewers that everything is resolved and that they can move ahead with approving Lumizyme. And that is what we believe has continued to take place. So I'm not sure whether we and when we will actually get a letter."

306. When an analyst asked why Defendants were so certain that the contamination would not affect the Lumizyme application, Lawton again insisted that the compliance issues had been resolved and did not concern Lumizyme:

> At the moment, this particular issue relates to Cerezyme. And as Dave said, we're addressing that for future manufacture. And we're talking with the FDA specifically around the release of the Cerezyme lots and what we need to do there to be able to ensure that that's okay, to release those lots.
>
> I am confident that we will also be discussing with FDA our plan for how we will clean the facility and how we plan to move forward. And so, that's very separate from Lumizyme, which we're not discussing with regard to the Allston manufacturing specifically at this point, because no lots are impacted.
>
> So the broader compliance issues that we have resolved, we expect the district office to inform the compliance organization that they are fully resolved as far as a warning letter. And therefore, FDA can, once they've completed their review of all of the other items, can go ahead and give us approval for Lumizyme.
>
> **Analyst**: So just to be clear, you've gotten feedback from FDA that this does not impact that timeline?

> **Lawton**: We have not discussed that. We have not discussed Lumizyme at this point, because we've been focusing on Cerezyme.

307. Lawton also insisted that there would not be another inspection required prior to Lumizyme approval:

> Yes, so let me first start by saying there does not need to be any reinspection. This is just an ongoing conversation with the FDA about our plans of how we'll clean the facility, how we plan to move forward and make sure that we can address this. And as Dave said, now we have this assay. We can use that to help us be confident that it's no longer there. And as long as we're updating the FDA on that and they know that those actions are taking place, then there is no need for FDA to have to actually reinspect or specifically ask for any other action other than knowing we're moving forward with those things.

308. Lawton also claimed that the contamination would have no impact on previously announced timelines for Lumizyme approval, and that the Company was still expecting approval by November 2009, but very likely earlier:

> So I think we actually put out in a press release that we had replied and provided FDA all of the information they needed to be able to process the Lumizyme approval, and that that was submitted in May. And that based on the fact that they received clinical information from our registry database that the FDA would be giving that a six-month PDUFA date from May, but that we also anticipate, given that we worked so closely with the FDA before we submitted that information, we do not believe that they are going to take that full six months before we received approval, because they are very familiar with all of the information we actually provided to them…. That's difficult for me to say when we would expect action. We continue, again, we know that they are reviewing it. We've had a couple of extra questions. So anytime between now and their PDUFA date.

309. Lawton also claimed that none of these events would have any effect on the Company's submission of an sBLA for approval of the 4000L product: "On the question with regards to the 4000-liter sBLA, this has absolutely no impact at all on that."

310. The statements in ¶¶ 304-309 were false and misleading, omitted material information, and lacked a reasonable factual basis when made for the reasons stated above at ¶ 220(C), 287, and because:

A. The contamination bore a direct relationship to their shoddy manufacturing practices, including, as the FDA would later identify, their failure to take necessary steps to prevent contamination. By Defendants' own admission, they had not identified the source of the contamination and thus could not be certain that it was unconnected to their failure to comply with CGMP. Defendants themselves stated that they believed that the virus had entered the plant through raw materials; as the FDA would later conclude, Defendants' handling of raw materials was one of the many areas in which they failed to comply with CGMP. Moreover, Defendants themselves would later admit in a private letter to the FDA that both the contamination and the deviations from CGMP resulted from systemic problems with the Company's quality control. *See* ¶¶144, 170-71, 184.

B. Defendants falsely claimed that the FDA had concluded that the issues raised in the February 2009 Warning Letter had been resolved. In fact, as described above at ¶¶ ¶¶ 55-84, 99, 101-02, 162, 170-71, 184-85, 192-93, these issues had not been resolved and would ultimately doom the Lumizyme BLA.

C. Moreover, Defendants Termeer, Meeker, Lawton, and Bamforth would soon admit in their undisclosed August 14, 2009 letter to the FDA that the viral contamination and compliance issues represented a systemic failure at both their Framingham and Allston plants. ¶¶ 170-71.

D. Defendants falsely claimed that the contamination would not affect the timeline for approval of Lumizyme, that Lumizyme would be approved within six months, and that no re-inspection would be required. As Defendants knew or were reckless in not knowing, the compliance issues at Allston had not been resolved. Defendants had not even discussed with the FDA whether the contamination would affect the Lumizyme BLA.

E. As Termeer would later admit on December 15, 2009, Genzyme management had determined back in March 2009 that they would submit Genzyme's application for approval of the 4000L material as a supplement to the Lumizyme BLA. Thus, approval of the 4000L material was directly dependent on Lumizyme approval. Because the contamination was directly related to Allston's continued compliance failures, and because Genzyme had still not resolved those failures, the sBLA for the 4000L product was jeopardized.

311. No Defendant corrected the misleading statements of the other Defendants on the conference call.

312. On June 24, 2009, Genzyme attended a conference with analysts where its executives discussed the Allston problems. When asked how the compliance issues and the contamination affected the approval process for Lumizyme, McDonough answered:

> With respect to the FDA review of the Allston facility related to the warning letter, the inspector has been to conduct their reinspection of the facility. We were informed verbally that that inspection had revealed that we had completed and substantially met all of the requirements that were outlined in that warning letter. We have not yet received formal confirmation of that in the form of a letter, but we don't believe that that letter is an essential part of the process from the perspective of resolving the specifics of the warning letter. More importantly, the warning letter is unrelated to the approval process for Lumizyme in the U.S.

> We were specifically made aware of that by the FDA and so we're not viewing those two things as gating items.
>
> Obviously, the FDA from the point of view of the Lumizyme approval, is working through a process as we told you before. We're expecting a PDUFA date in the November timeframe. Our strong expectation is that we will have an interaction and an approval with the FDA in a timeframe shorter than that November PDUFA date, but that's formally the date that we're obviously looking forward to in communicating with this community.

313. McDonough also repeated Lawton's prior assurances that the contamination was unrelated to the "points that were in the warning letter."

314. At a conference for analysts held the next day, June 25, 2009, in Cambridge, Massachusetts, McDonough repeated his assertions that the Company had received verbal assurances from the FDA that the Allston plant was in compliance, that the compliance issues outlined in the February 2009 Warning Letter were unrelated to the approval of the Lumizyme BLA. He also stated that re-inspection of the plant was unlikely and that any re-inspection was likely to be minor and would not impact the expected approval of Lumizyme in November 2009. McDonough also reiterated the Company's intention to market Lumizyme commercially, explaining that after Lumizyme was approved, the Company expected to quickly transition patients who had previously been receiving Myozyme under temporary access programs to full-paying customers.

315. The statements in ¶¶ 312-14 were false and misleading, omitted material information, and lacked a reasonable factual basis when made for the reasons given above at ¶¶ 199, 220(C), 287, 310(B). Additionally, McDonough's claim that the February 2009 Warning Letter was unrelated to the Lumizyme approval was false. As the Company itself had admitted in its 2008 10-K, "A satisfactory resolution of the FDA's warning letter is required before the agency will approve our application for alglucosidase alfa produced at the 2000L scale."

Ultimately, the Company would admit that Allston's ongoing compliance issues had doomed the Lumizyme application entirely.

316. On July 22, 2009, Genzyme held a conference call in which defendants Termeer, Meeker, Lawton, Wyzga, and McDonough participated to discuss its second quarter results. Lawton reiterated Defendants' prior statement that the Company had remedied the problems in the February 2009 Warning Letter to the FDA's satisfaction: "I think we had already communicated that the FDA had indeed been out and confirmed that we had addressed all of the outstanding items in the warning letter, and at this point we believe that that's being communicated, or we'd anticipate that that's being communicated within the FDA, and we do not anticipate that that would be a rate limiting step for the Lumizyme approval either at this point."

317. Lawton's statement was false and misleading for the reasons stated at ¶¶ 287 (A-B) and 310(B). No Defendant corrected Lawton's statement.

318. On October 21, 2009, Genzyme issued a press release, filed on Form 8-K with the SEC, reporting its results for the third quarter ended September 30, 2009. The release stated that "The PDUFA date for Lumizyme (the 2000 L product) is November 14. Upon approval, Genzyme plans to submit a supplemental BLA for the 4000 L process. A standard review period is four months, which would mean an FDA action date by the end of March 2010." On a conference call with analysts later that same day in which Termeer, Wyzga, Meeker, McDonough, and Lawton participated, Termeer stated that "nothing has changed" with respect to the Lumizyme timeline. McDonough concurred, stating that "[a]s we stated in the release, the PDUFA date for Lumizyme is coming up and should allow us to submit an sBLA soon thereafter

to support transition to the 4000-liter product in the U.S. anticipated as Henri [Termeer] said at the end of the First Quarter in 2010."

319. On November 2, 2009, Defendants filed their Report on Form 10-Q for the third quarter ended September 30, 2009, signed by Wyzga, and containing certifications signed by Termeer and Wyzga as required by the Sarbanes-Oxley Act of 2002, 15 U.S.C.A. §§ 7201 *et seq*. The Form 10-Q stated that the FDA inspection was still ongoing. Despite this fact, and despite all of the undisclosed problems at Allston that they had experienced and were continuing to experience, Defendants still insisted that Lumizyme would be approved on the PDUFA date in November 2009, with approval for the sBLA for the 4000L product following in March 2010: "The FDA's target action date under the Prescription Drug User Fee Act, or PDUFA, for Lumizyme is November 14, 2009. We expect to submit a supplemental BLA for the 4000L process upon approval of Lumizyme. A standard review period is four months, which would mean an FDA action date by the end of March 2010."

320. The statements in ¶¶ 318-19 were false and misleading, omitted material information, and lacked a reasonable factual basis when made for the reasons stated above at ¶¶ 287 (A-B) and 310(B). No Defendant corrected the misleading statements of the other Defendants on the conference call.

VI. LOSS CAUSATION

321. Throughout the Class Period, Defendants' materially false and misleading statements and omissions concerning Genzyme's supply and manufacturing issues and projected earnings caused Genzyme's stock price to be artificially inflated. As a result of Defendants' false and misleading statements and material omissions, Genzyme's common stock traded at artificially inflated levels throughout the Class Period, reaching a Class Period high of $83.25 on August 14, 2008.

322. Plaintiffs and the other members of the Class suffered damages as a direct result of Defendants' fraudulent conduct described in this Complaint. But for Defendants' misrepresentations and omissions, Plaintiffs and the other members of the Class would not have purchased Genzyme's stock, or would not have purchased it at artificially inflated prices. As the reality of Defendants' conduct and the true picture of Genzyme's manufacturing operations, financial position, and business prospects were gradually revealed to the investing public, the price of Genzyme common stock declined significantly in response to those revelations, as described above, causing damages to Plaintiffs and other Class members.

VII. ADDITIONAL ALLEGATIONS OF SCIENTER

323. The Defendants acted with scienter in that they knew or recklessly disregarded that the public documents and statements issued by them were materially false and/or misleading; knew that such statements would be disseminated to the investing public; and knowingly and substantially participated in the issuance and dissemination of the public documents and statements. In addition, Defendants acted with scienter by intentionally failing to inform the market in a timely manner of material information. As detailed above, and summarized by the additional scienter allegations set forth below, Defendants' intent to deceive and/or reckless disregard for the truth is demonstrated by direct evidence as well as circumstantial evidence supporting a strong inference of scienter.

324. Beyond the responsibility to take ***corrective*** action to address noncompliance with CGMP, senior management of drug manufacturers are responsible for ***preventing*** such noncompliance. Thus, plausible deniability, which executives in another industry might assert, is, by regulation, not available to FDA-regulated drug manufacturers. Since before the commencement of the Class Period, Defendants failed to prevent noncompliance with applicable

CGMP. Rather, Defendants maintained a culture of noncompliance at Genzyme's highest echelons of management dating back to at least 1998.

325. In May 1998, FDA inspectors identified numerous deficiencies while auditing a study that Genzyme had performed in support of an application to sell a diagnostic kit. As a result, the FDA sent Genzyme a Form 483 listing at least six deviations from compliance with FDA regulations, all of which had been discussed with David H. Schubert, Genzyme's Director of Regulatory Affairs, at the conclusion of the inspection. When Genzyme failed to correct the deficiencies, the FDA sent Termeer a warning letter on July 22, 1998. The letter stated that, among other things, Genzyme had failed to implement certain procedures to which it had committed in 1996. As a result of the warning letter, Genzyme's application for the diagnostic kit was placed on hold.

326. Just six months later, in January 1999, the FDA issued another Form 483 noting four deviations from CGMP at Genzyme's Framingham, Massachusetts plant. Among other things, the Form 483 stated that Genzyme's CAPA program did not address verification or validation of the action to be correctied or prevented. In a March 1, 2000 report by *Validation Times*, Dale Audet, Genzyme's Vice President of Quality Assurance, stated that Genzyme's CAPA consisted of notifying other Genzyme facilities of similar problems that might occur but – incredibly – that Genzyme had "no control over implementation of any preventive measures at other facilities."

327. In 2001, the FDA issued another Form 483 and warning letter concerning Genzyme's Ridgefield, New Jersey facility. In it, the FDA cited Genzyme's deficiencies regarding CAPA; production and process controls; management controls; and design controls. These problems were sufficiently severe that the warning letter, addressed to Termeer, informed

him that "the specific violations … may be symptomatic of serious underlying problems within your establishment's quality system. *You are responsible for investigating and determining the causes of the violations identified by the FDA.* If the causes are determined to be system problems, you must promptly initiate permanent corrective and preventive actions." (emphasis added). The letter noted that new products would not be approved until the deficiencies were corrected.

328. Just months before the start of the Class Period, the FDA conducted an inspection of Genzyme's plant in Lyon, France and noted additional, significant deviations from CGMP, prompting the FDA to issue yet another Form 483. When Genzyme failed to correct the deficiencies, the FDA issued a Warning Letter on September 19, 2007 addressed to Termeer. The warning letter found Genzyme to be out of compliance with CGMP in numerous areas, including production and process controls; investigation into "Adverse Events"; and buildings and facilities. In particular, the letter stated that in several instances, Genzyme continued manufacturing despite excessive levels of bacteria in early batches of the drug produced at the Lyon facility, and did not conduct sufficiently comprehensive investigations of these failures. Although the final product met specifications, the FDA stated:

> [T]here is a high probability that the observed CGMP deviations, if not corrected, would substantially increase the risk of future product failures. Of particular concern is that you continued to use components and intermediates that did not meet your internal in-process limits and you did not fully investigate these deviations and implement appropriate corrective and preventive actions. Adequate process control and correcting and preventing deficiencies in the process before they result in product failures are underlying principles of CGMP.

329. With respect to violations of CGMP governing buildings and facilities, the FDA found that contaminants (spore forming microorganisms, *i.e.*, mold) had been routinely found since 2004. In fact, the FDA reminded Genzyme that the failure to adequately evaluate its disinfectants was a "repeat observation" from the FDA's 2004 inspection. The FDA informed

Termeer that the manufacturing process was "not in a state of control" and that Genzyme's proposed solutions to the deficiencies were inadequate.

330. Thus, by the time the Class Period commenced, and throughout the Class Period, Defendants and other members of Genzyme senior management were well apprised that Genzyme had repeatedly violated CGMP and had to remedy those violations in order to avoid severe regulatory consequences and obtain approval of future BLAs. Nevertheless, Genyzme's senior management, including the Individual Defendants, knew or recklessly disregarded systemic quality control problems by at least the beginning of the Class Period.

331. The Individual Defendants were active participants in the management of Genzyme, which involved ensuring that its manufacturing facilities were operating properly in order to sustain supply for its core products and that any regulatory requirements impacting the manufacturing facilities had been met. Throughout the Class Period, Termeer was aware that the Company was experiencing systemic compliance dating back to at least as early as the Spring of 1998, and he knew no later than September 19, 2007 about the CGMP deviations that were set forth in the FDA's Warning Letter sent to him on or about that day. As a recipient of the October 2008 483 pursuant to FDA Field Management Directive 120, and the Warning Letter, Termeer was unquestionably aware of the CGMP deviations discussed therein.

332. Additionally, as described above at ¶ 44, FDA regulations require senior corporate management to oversee regulatory compliance. Pursuant to standard industry procedures, the managers of the Allston plant would have updated senior Genzyme executives, especially those involved in Quality and Regulatory Compliance, every night during the FDA inspections of Allston, and communicated their observations. Therefore, Termeer and the other Individual Defendants knew – or were reckless in not knowing – that the supply of Genzyme's

drugs was at risk and that violations of the FDA's CGMP would jeopardize the Company's ability to continue making its products and obtain approval of Lumizyme. However, Termeer and the other Individual Defendants failed to disclose these problems, or their potential impact on Genzyme's financial results and operations, to investors in a timely fashion.

333. Defendants – by virtue of their receipt of information reflecting the true facts regarding Genzyme and its business, operations and manufacturing and quality control deficiencies, and their control over false and misleading statements and omissions concerning Genzyme – were active and culpable participants in the fraudulent scheme alleged herein. Defendants knew and/or recklessly disregarded the false and misleading nature of the information which they caused to be disseminated to the investing public. The ongoing fraudulent scheme described in this complaint could not have been perpetrated over a substantial period of time, as has occurred, without the knowledge and complicity of the personnel at the highest level of the Company, including the Individual Defendants.

334. Each of the Defendants had actual knowledge or was reckless in not knowing of Genzyme's manufacturing and quality control deficiencies and the adverse effects thereof because, *inter alia*:

- Prior to the start of the Class Period, Genzyme received three Warning Letters and at least four Form 483s from the FDA. As set forth above, each of these Warning Letters and FDA 483s informed Genzyme's management of numerous, widespread and significant manufacturing and quality control deficiencies in violation of CGMP;

- Each of the Defendants was aware that the Allston plant, which was of critical importance to the Company and therefore the focus of management attention, was operating beyond capacity, and that (as a result of the Company's decision to add Myozyme production lines to the Allston plant) the Company was forced to reduce its inventories of Cerezyme and Fabrazyme without adequately replacing them with fresh product;

- Each of the Individual Defendants was a corporate-level officer of Genzyme and either saw or was aware of the contents of the October 2008 483 and the February 2009 Warning Letter during the Class Period.

- It is standard procedure in any drug manufacturing company to hold meetings among high-level executives, in particular those tasked with Quality Assurance and Regulatory duties, to review any communication from the FDA. Here, Lawton and Meeker in particular were responsible for overseeing Quality and Regulatory Affairs, and in those capacities were made aware of the FDA's observations and were in contact with the FDA throughout the Class Period to discuss its concerns about Allston and the status of the Lumizyme BLA.

- As Defendants admitted at the end of the Class Period, each of the Defendants was aware that as of March 2009, the Company did not intend to produce Lumizyme for commercial sale in the United States.

335. Genzyme, in its public filings, acknowledged the importance of compliance with CGMP regulations. The February 2009 Warning Letter, the October 2008 483 and November 2009 483, together with the warning letters and Form 483s received prior to the Class Period, established that there were serious and pervasive deficiencies across the entire range of manufacturing and quality control operations at Genzyme's facilities. The February 2009 Warning Letter and October 2008 483 also established that the three drugs that accounted for nearly 50% percent of the Company's 2008 product revenues (Cerezyme, Fabrazyme, and Myozyme) were affected by manufacturing and quality control deficiencies at Allston. Given the importance of CGMP compliance, the serious and widespread nature of the deficiencies, and the significance of the products involved, the Individual Defendants were aware throughout the Class Period of, or recklessly disregarded, the Company's manufacturing and quality control deficiencies and the severe threat they posed to Genzyme's ability to continue manufacturing adequate supplies of its existing core products, as well as its ability to obtain FDA approval of additional products.

336. Defendants knew, as was acknowledged in Genzyme's public filings, that "[a]s part of product approval, the manufacturer of the product must undergo a pre-approval Good Manufacturing Practices inspection (for a drug or biologic) from the FDA." They also knew that Genzyme's BLA for Lumizyme could not be approved without a pre-approval inspection of the

firm's Allston facility and that the Company's history of CGMP violations would subject its BLA for Lumizyme to a higher level of scrutiny. They were also aware, through the FDA inspections, that, *inter alia*: the Company's plants and equipment were inadequate and outdated; its quality control personnel were insufficient in number and lacked adequate experience and expertise; and its manufacturing processes and procedures were inadequate to ensure that drug products were produced with the requisite strength, quality, purity and safety.

337. Defendants were motivated to conceal the true extent of Genzyme's manufacturing deficiencies and CGMP violations because: (a) acknowledgement of such deficiencies – both to the FDA and to the public – would increase the likelihood that the FDA would delay approval of Lumizyme; and (b) public confidence in the safety and effectiveness of the Company's drug products would be undermined.

VIII. NO SAFE HARBOR

338. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this complaint. The specific statements pleaded herein either were not identified as "forward-looking statements" when made, or to the extent there were any statements identified as forward-looking, there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. Alternatively, to the extent that the statutory safe harbor does apply to any forward-looking statements pleaded herein, Defendants are liable for those false, forward-looking statements because at the time each of those forward-looking statements was made, the particular speaker knew that the particular forward-looking statement was false and lacked a reasonable basis, and/or the forward-looking statement was authorized and/or approved by an executive officer of Genzyme who knew that those statements were false and lacked a reasonable basis when made.

IX. CLASS ACTION ALLEGATIONS

339. Plaintiffs bring this action as a class action pursuant to Rules 23(a) and 23(b)(3) of the Federal Rules of Civil Procedure, on behalf of Plaintiffs and a Class consisting of all those who purchased common stock of Genzyme between and including October 24, 2007 and November 13, 2009 and who were damaged as a consequence. Excluded from the Class are Defendants; members of the immediate families of each of the Individual Defendants; each subsidiary, affiliate, and controlling person of any such person or entity; those who were officers, directors or insurers of Genzyme during the Class Period; and the legal representatives, heirs, successors or assigns of each such excluded party.

340. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Genzyme's common stock was actively traded on the Nasdaq stock exchange. According to the Company's 2008 Form 10-K, there were 271,352,703 shares of Genzyme common stock outstanding as of January 31, 2009. While the exact number of Class members is unknown to Plaintiffs at this time, Plaintiffs believe that there are thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Genzyme or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

341. Plaintiffs' claims are typical of the claims of the members of the Class, as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of the federal securities laws.

342. Plaintiffs will fairly and adequately protect the interests of the members of the Class and have retained counsel competent and experienced in class and securities litigation.

343. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

a. whether the federal securities laws were violated by Defendants' conduct as alleged in this Complaint;

b. whether statements made by Defendants to the investing public during the Class Period misrepresented and/or omitted material facts;

c. whether reliance upon Defendants' misrepresentations and/or omissions may be presumed;

d. whether Defendants acted with scienter; and

e. to what extent the members of the Class have sustained damages and the proper measure of damages.

344. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impracticable for members of the Class to individually redress the wrongs done to them. Plaintiffs anticipate no difficulty in the management of this action as a class action.

X. APPLICABILITY OF PRESUMPTION OF RELIANCE: THE FRAUD-ON-THE-MARKET DOCTRINE

345. At all relevant times, the market for Genzyme's common stock was an efficient market for the following reasons, among others:

a. Genzyme's stock met the requirements for listing, and was listed and actively traded on the Nasdaq stock exchange, a highly efficient and automated market;

b. During the Class Period, the average weekly trading volume of Genzyme's stock was greater than two percent of the outstanding shares, justifying a strong presumption that the market for Genzyme's shares was efficient;

c. As a regulated issuer, Genzyme filed periodic public reports with the SEC and the Nasdaq stock exchange;

d. Genzyme regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services;

e. Genzyme was followed by over twenty securities analysts who wrote reports that were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace;

f. There was a cause-and-effect relationship between unexpected corporate events or financial releases and movements in the stock price; and

g. Genzyme was eligible to register its stock pursuant to a Form S-3 registration statement.

346. The market for Genzyme's common stock promptly digested current information regarding Genzyme from all publicly-available sources and reflected such information in Genzyme's stock price. Under these circumstances, it is appropriate to presume that all purchasers of Genzyme common stock during the Class Period relied on the misstatements and omissions by Defendants.

COUNT I

VIOLATION OF SECTION 10(b) OF THE EXCHANGE ACT AND RULE 10b-5 (AGAINST ALL DEFENDANTS)

347. Plaintiffs repeat and reallege each and every allegation above as if set forth fully herein.

348. This Claim is brought pursuant to Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder, on behalf of Plaintiffs and all other members of the Class.

349. As alleged in this Complaint, throughout the Class Period, Defendants, individually and in concert, directly and indirectly, by the use of the means or instrumentalities

of interstate commerce, the mails and/or the facilities of a national securities exchange, made false and/or misleading statements of material fact and/or omitted to state material facts necessary to make the statements made not misleading, in violation of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder. Among other things, Genzyme's SEC filings and press releases contained materially false and misleading statements of fact and omitted material facts as detailed above.

350. Defendants' false and misleading statements and omissions were intended to and did, as alleged herein, (i) deceive the investing public, including Plaintiffs and the other members of the Class; (ii) artificially inflate and maintain the market price of Genzyme's securities; and (iii) cause Plaintiffs and the other members of the Class to purchase Genzyme's securities at inflated prices.

351. Defendants were each individually and collectively responsible for making one or more of the statements and omissions alleged herein, by virtue of having (i) prepared, reviewed, commented on, approved, signed, and/or disseminated documents which contained false and/or misleading statements of material fact and/or omitted facts necessary to make the statements therein not misleading, and/or (ii) made oral statements during analyst conference calls that were false and misleading, omitted material facts, and lacked a reasonable factual basis.

352. Defendants made the false and/or misleading statements and omissions knowingly and intentionally, or in such an extremely reckless manner as to constitute willful deceit and fraud upon Plaintiffs and other members of the Class who purchased Genzyme's common stock during the Class Period.

353. Defendants' false and/or misleading statements and omissions were made in connection with the purchase or sale of Genzyme's common stock.

354. In ignorance of the false and misleading nature of Defendants' statements and omissions, and relying directly or indirectly on those statements and/or upon the integrity of the market price for Genzyme's common stock, Plaintiffs and the other members of the Class purchased Genzyme's common stock at artificially inflated prices during the Class Period. But for the fraud committed by the Defendants, Plaintiffs and the members of the Class would not have purchased these securities at artificially inflated prices.

355. The market price for Genzyme's common stock declined materially upon the public disclosure of the facts that had previously been misrepresented or omitted by Defendants, as described above.

356. Plaintiffs and the other members of the Class were substantially damaged as a direct and proximate result of their purchases of Genzyme's common stock at artificially inflated prices and the subsequent decline in the price of those securities when the truth was revealed.

COUNT II

VIOLATION OF SECTION 20(a) OF THE EXCHANGE ACT (AGAINST TERMEER, MEEKER, LAWTON, BAMFORTH, MCDONOUGH, AND WYZGA)

357. Plaintiffs repeat and reallege each and every allegation above as if set forth fully herein.

358. This Claim is brought on behalf of Plaintiffs and all other members of the Class against defendants Termeer, Meeker, Lawton, Bamforth, McDonough, and Wyzga, pursuant to Section 20(a) of the Exchange Act.

359. Throughout the Class Period, Termeer was a controlling persons of Genzyme within the meaning of Section 20(a) of the Exchange Act. By virtue of his positions as President, Chief Executive Officer and Chairman of the Board of Directors of Genzyme, Termeer had the power to influence and control and did influence and control, directly or

indirectly, the decision-making of Genzyme, including the content and dissemination of the various statements that Plaintiffs contend are materially false and misleading. Termeer was provided with or had unlimited access to copies of Genzyme's press releases and public filings alleged by Plaintiffs to be false and/or misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements, cause the statements to be corrected, or cause the statements to be made at an earlier time. Termeer is also charged by the FDA with the responsibility for Genzyme's compliance with all CGMP.

360. Throughout the Class Period, defendants Bamforth, Lawton, Meeker and McDonough were controlling persons of Genzyme within the meaning of Section 20(a) of the Exchange Act. By virtue of their respective positions as Senior Vice President, Corporate Operations and Pharmaceuticals; Senior Vice President, Global Market Access; Executive Vice President (overseeing Genzyme's Therapeutics and Biosurgery business units and Global Corporate Operations); and Senior Vice President (heading Genzyme's Personal Genetic Health's business units), Bamforth, Lawton, Meeker and McDonough had the power to influence and control and did influence and control, directly or indirectly, the decision-making of Genzyme, including the content and dissemination of the various statements that Plaintiffs contend are materially false and misleading. In particular, Bamforth, Lawton, Meeker and McDonough communicated with the market on behalf of Genzyme during analyst conference calls regarding the Company's compliance with FDA regulations, the Company's efforts to address the issues raised in the October 2008 483 and the Warning Letter, and the likely approval of the Lumizyme BLA. Bamforth, Lawton, Meeker and McDonough were provided with or had unlimited access to copies of Genzyme's press releases and public filings alleged by Plaintiffs to be false and/or misleading prior to and/or shortly after these statements were issued and had the

ability to prevent the issuance of the statements, cause the statements to be corrected, or cause the statements to be made at an earlier time.

361. Throughout the Class Period, defendant Wyzga was a controlling person of Genzyme within the meaning of Section 20(a) of the Exchange Act. By virtue of his positions as Chief Financial and Accounting Officer, and an Executive Vice President, Finance, Wyzga had the power to influence and control and did influence and control, directly or indirectly, the decision-making of Genzyme, including the content and dissemination of the various statements that Plaintiffs contend are materially false and misleading. In particular, Wyzga was a signatory to the Company's Form 10-K filings and communicated with the market during analyst conference calls. Wyzga was provided with or had unlimited access to copies of Genzyme's press releases and public filings alleged by Plaintiffs to be false and/or misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements, cause the statements to be corrected, or cause the statements to be made at an earlier time.

362. As set forth above, Genzyme violated Section 10(b) and Rule 10b-5 by its acts and omissions as alleged herein. As a direct and proximate result of Genzyme's wrongful conduct, Plaintiffs and the Class suffered damages. As controlling persons of Genzyme, Termeer, Bamforth, Meeker, Lawton, McDonough, and Wyzga are jointly and severally liable pursuant to Section 20(a) of the Exchange Act for Genzyme's violations of Section 10(b) and Rule 10b-5.

PRAYER FOR RELIEF

363. WHEREFORE, Plaintiffs demand judgment:

A. Determining that this action is a proper class action pursuant to Rule 23 of the Federal Rules of Civil Procedure;

B. Awarding compensatory damages against Defendants in favor of Plaintiffs and all Class members for damages sustained as a result of Defendants' wrongdoing;

C. Awarding Plaintiffs and all Class members their costs and disbursements in this suit, including reasonable attorneys' fees and expert fees; and

D. Awarding such other relief as the Court deems just and proper.

JURY DEMAND

364. Plaintiffs, on behalf of themselves and the Class, hereby demand a trial by jury.

Dated: March 1, 2010

Respectfully submitted,

/s/ Jeffrey C. Block

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Additional Plaintiffs' Counsel

CERTIFICATION ON BEHALF OF DEKA INTERNATIONAL S.A. LUXEMBURG

The undersigned individuals, as authorized signatories of co-lead plaintiff Deka International S.A. Luxemburg ("DEKA"), make this Certification pursuant to 28 U.S.C. § 1746 and 15 U.S.C. § 78u-4, and state as follows:

1. We have reviewed the Consolidated Class Action Complaint in the securities class action lawsuit captioned *In re Genzyme Corp. Securities Litigation*, No. 1:09-cv-11267-GAO (D. Mass.), and have authorized its filing.

2. Attached as **Schedule A** to this Certification is a list of DEKA's transactions in the common stock of Genzyme Corporation ("Genzyme") during the class period set forth in the Consolidated Class Action Complaint.

3. DEKA did not purchase the securities of Genzyme at the direction of counsel or in order to participate in any private action arising under the federal securities laws. DEKA invested in Genzyme securities solely for its own business purposes.

4. DEKA is willing to serve as a lead plaintiff in a representative capacity on behalf of the proposed class of persons who purchased Genzyme securities during the class period, including providing testimony at deposition and trial, if necessary.

5. During the three-year period preceding the date of its Certification in support of its motion for appointment of lead plaintiff, DEKA had served or sought to serve as a representative party for a class in an action under the federal securities laws in the following securities class actions:

In re General Motors Sec. Litig., Civ. No. 06-1749 (E.D. Mich.), transferred from Civ. No. 05-8088 (S.D.N.Y.) (Appointed)

Selbst v. The Coca-Cola Company, Civ. No. 05-1226 (N.D. Ga.) (Appointed)

Kadugian v. Harley-Davidson, Inc., Civ. No. 05-547 (E.D. Wis.) (Appointed)

In re Fannie Mae 2008 Sec. Litig., Civ. No. 08-7831 (S.D.N.Y.) (Not Appointed)

6. DEKA will not accept any payment for serving as a representative party on behalf of the class beyond its *pro rata* share of any recovery, except as ordered and approved by the court.

We declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

Dated: February 24, 2010

Deka International S.A. Luxemburg

Rainer Mach

Holger Knüppe

SCHEDULE A

DEKA (DIL)

Transactions in Genzyme Corp.

Cusip: 372917104
Ticker: GENZ
Period: October 24, 2007 through November 13, 2009

Class Period Purchases		
Trade Date	Quantity	Price
06/27/08	55,000	$72.56
06/27/08	120,500	$72.56
07/02/08	27,000	$72.44
07/16/08	4,900	$79.30
02/17/09	4,187	$71.23
02/24/09	1,490	$70.42
03/09/09	22,600	$53.97
04/20/09	5,300	$54.99
06/02/09	11,700	$59.73
06/04/09	12,200	$63.24

Class Period Sales		
Trade Date	Quantity	Price
01/24/08	100	$74.82
01/28/08	100	$73.83
10/08/08	9,150	$69.84
10/20/08	23,500	$63.84
10/20/08	26,250	$64.19
12/02/08	18,500	$59.59
02/24/09	28,000	$70.52
03/10/09	22,600	$55.64
09/02/09	700	$55.09
10/22/09	13,000	$52.25

CERTIFICATION ON BEHALF OF THE CITY OF EDINBURGH COUNCIL AS ADMINISTRERING AUTHORITY OF THE LOTHIAN PENSION FUND

I, Clare Scott, on behalf of co-lead plaintif City of Edinburgh Council as Administering Authority of the Lothian Pension Fund ("Lothian"), make this Certification pursuant to 28 U.S.C. § 1746 and 15 U.S.C. § 78u-4, and state as follows:

1. I am the Head of Investment and Pensions for Lothian, and am duly authorized to make this Certification on behalf of Lothian.

2. I have reviewed the Consolidated Class Action Complaint in the securities class action lawsuit captioned *In re Genzyme Corp. Securities Litigation*, No. 1:09-cv-11267-GAO (D. Mass.), and have authorized its filing on behalf of Lothian.

3. Attached as **Schedule A** is a list of all of Lothian's transactions in the common stock of Genzyme Corporation ("Genzyme") during the class period set forth in the Consolidated Class Action Complaint.

4. Lothian did not purchase the securities of Genzyme at the direction of counsel or in order to participate in any private action arising under the federal securities laws. Lothian invested in Genzyme securities solely for its own business purposes.

5. Lothian is willing to serve in a representative capacity on behalf of the proposed class of persons who purchased Genzyme securities during the Class Period, including providing testimony at deposition and trial, if necessary.

6. During the three-year period preceding the date of its Certification in support of its motion for appointment of lead plaintiff, Lothian had served or sought to serve as a representative party for a class in an action under the federal securities laws in the following securities class actions:

Smith, et al. v. Eli Lilly and Co., et al., No. 07 Civ. 1310 (E.D.N.Y.) (not appointed)

Connecticut Retirement v. Amgen Inc., et al., No. 07 Civ. 2536 (C.D. Cal.) (not appointed)

Steinberg v. Ericsson LM Telephone Co., No. 07 Civ. 9615 (S.D.N.Y.) (not appointed)

City of Edinburgh Council on Behalf of the Lothian Pension Fund v. Vodafone Group Public Co., No. 07 Civ. 9921 (S.D.N.Y.) (appointed)

City of Taylor General Employees Retirement System v. Sanofi-Aventis, et al., No. 07 Civ. 10279 (S.D.N.Y.) (appointed)

Reese v. Brown, et al., No. 08 Civ. 1008 (W.D. Wash), transferred from No. 07 Civ. 7511 (C.D. Cal.) (appointed)

In re Lehman Brothers Equity/Debt Securities Litigation, No. 08 Civ. 5523 (appointed)

In re Elan Corp. Securities Litigation, No. 08 Civ. 8761 (S.D.N.Y.) (not appointed)

7. Lothian will not accept any payment for serving as a representative party on behalf of the class beyond its *pro rata* share of any recovery, except as ordered and approved by the court.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

Dated: February 27, 2010

City of Edinburgh Council as Administering
Authority of the Lothian Pension Fund

Clare Scott, Head of Investment and Pensions

SCHEDULE A

Lothian

Transactions in Genzyme Corp.

Cusip: 372917104
Ticker: GENZ
Class Period: October 24, 2007 through November 13, 2009

Class Period Purchases		
Trade Date	**Quantity**	**Price**
08/14/08	23,400	$82.44
08/14/08	4,598	$82.76
08/14/08	6,502	$82.76
08/14/08	15,200	$80.85
08/15/08	30,300	$83.37
08/15/08	3,700	$83.50
08/20/08	4,300	$81.52
08/21/08	6,400	$79.44
08/26/08	3,200	$78.89
08/27/08	6,500	$78.04
09/04/08	12,900	$77.18
10/08/08	11,200	$70.88
11/26/08	3,200	$65.37
03/04/09	5,600	$53.66
04/15/09	1,538	$55.48
05/26/09	3,922	$58.97
06/03/09	3,812	$62.25
06/17/09	3,800	$54.96
06/17/09	3,900	$54.87
06/22/09	15,696	$53.60
08/04/09	1,000	$49.47

Class Period Sales		
Trade Date	**Quantity**	**Price**
10/29/08	9,600	$71.10
01/30/09	9,900	$68.63
02/02/09	6,300	$69.39
02/02/09	3,400	$69.39
07/16/09	7,600	$54.03
07/16/09	14,600	$54.14
07/29/09	2,398	$54.41
07/31/09	34,100	$51.87
08/24/09	6,513	$53.57
09/03/09	9,916	$55.13
09/25/09	2,500	$56.66
10/15/09	28,600	$56.28
10/21/09	28,100	$53.38

CERTIFICATION PURSUANT TO
THE FEDERAL SECURITIES LAWS

I, Joe T. San Agustin, on behalf of Government of Guam Retirement Fund ("GGRF"), hereby certify, as to the claims asserted under the federal securities laws, that:

1. I am the Chairman of GGRF. I have reviewed the amended complaint in this matter and authorize its filing.

2. GGRF did not purchase the securities that are the subject of this action at the direction of counsel or in order to participate in any action arising under the federal securities laws.

3. GGRF fully understands the duties and responsibilities of the lead plaintiff under the Private Securities Litigation Reform Act, including the selection and retention of counsel and overseeing the prosecution of the action for the Class.

4. GGRF transactions in Genzyme Corp. during the Class Period are set forth in the chart attached hereto.

5. GGRF has sought to serve and was appointed as a lead plaintiff and representative party on behalf of a class in the following actions under the federal securities laws filed during the three-year period preceding the date of this Certification:

In re Lehman Brothers Equity/Debt Securities Litigation, Case No. 08-cv-5523 (S.D.N.Y.)
In re Wells Fargo Mortgage-Backed Certificates Litigation, Case No 09-cv-1376 (N.D. Cal.)

6. GGRF has sought to serve as a representative party on behalf of a class in the following actions under the federal securities laws filed during the three-year period preceding the date of this Certification:

Orange County Employees' Retirement System, et al. v. Carlson, et al.,
Case No. 09-cv-999 (N.D. Cal.)

7. GGRF will not accept any payment for serving as a representative party on behalf of the Class beyond GGRF's pro rata share of any recovery, except such reasonable costs and expenses (including lost wages) directly relating to the representation of the Class, as ordered or approved by the court.

I declare under penalty of perjury that the foregoing is true and correct. Executed this 26th day of February, 2010.

Joe T. San Agustin
Chairman
Government of Guam Retirement Fund

Government of Guam Retirement Fund
Transactions in Genzyme Corp.

Transaction	Date	Shares	Price
Purchases	9/10/2008	17,800	78.9800
Purchases	9/12/2008	7,900	80.1558
Purchases	9/24/2008	17,200	79.0532
Purchases	10/10/2008	8,300	63.3683
Purchases	10/28/2008	15,200	72.3024
Purchases	12/29/2008	8,700	65.0413
Purchases	12/29/2008	15,800	65.0413
Purchases	3/9/2009	11,000	53.8722
Sales	3/25/2009	(12,600)	56.7314
Sales	3/31/2009	(3,400)	60.0000
Sales	4/13/2009	(500)	55.5800
Sales	4/13/2009	(3,300)	55.7317
Sales	4/22/2009	(1,400)	51.4173
Sales	4/22/2009	(5,100)	52.3547
Sales	4/22/2009	(4,100)	51.5798
Sales	4/23/2009	(23,100)	52.1715
Sales	4/23/2009	(5,300)	51.7596
Sales	4/23/2009	(1,400)	51.0029
Sales	4/24/2009	(9,200)	53.1429
Sales	4/27/2009	(5,700)	54.3692
Sales	9/3/2009	(9,500)	55.2354
Sales	9/8/2009	(8,700)	55.6003
Sales	9/9/2009	(8,600)	55.5963

CERTIFICATE OF SERVICE

I, Jeffrey C. Block, hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing and paper copies will be sent to those indicated as non-registered participants on March 1, 2010.

Dated: March 1, 2010

/s/ Jeffrey C. Block
Jeffrey C. Block (BBO#600747)